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ABSTRACT

The text of a Senate hearing called to review federal efforts combating acquired immune deficiency syndrome (AIDS) is presented in this document. Opening statements reviewing the AIDS crisis are given by Senators Edward Kennedy and Lowell Weicker, Jr. Prepared statements are included by Senators Orrin Hatch and Ted Stevens. David Baltimore and Sheldon Wolff, co-chairs of the Committee on a National Strategy for AIDS, National Academy of Sciences, discuss findings and highlights from their recent report, "Confronting AIDS," make recommendations to deal with the problems posed by the AIDS epidemic, and stress the need for public education. Witnesses focusing on the development of an AIDS vaccine include: (1) Anthony Fauci, coordinator of AIDS research at the National Institutes of Health; (2) David Martin, Jr., Genentech, Inc.; and (3) Samuel Katz, professor at Duke University School of Medicine and member of the Institute of Medicine Panel on Vaccine Development. Jonathan Mann, director of the Special Program on AIDS, World Health Organization, discusses AIDS as a global health problem. Robert Windom, Assistant Secretary for Health, Department of Health and Human Services, and C. Everett Koop, United States Surgeon General, provide an update on federal information and education initiatives to prevent and control the spread of AIDS. The "Surgeon General's Report on Acquired Immune Deficiency Syndrome" is included. (NB)

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AIDS EPIDEMIC

ED290988

HEARING

BEFORE THE

COMMITTEE ON
LABOR AND HUMAN RESOURCES
UNITED STATES SENATE

ONE HUNDREDTH CONGRESS

FIRST SESSION

ON

REVIEWING FEDERAL EFFORTS BEING CONDUCTED TOWARD COMBATING THE AIDS EPIDEMIC

JANUARY 16, 1987

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AIDS EPIDEMIC

THURSDAY, JANUARY 15, 1987

U.S. SENATE,
COMMITTEE ON LABOR AND HUMAN RESOURCES,
Washington, DC.

The Committee met, pursuant to notice at 10:02 a.m., in Room SD-430, Dirksen Senate Office Building, Senator Edward M. Kennedy (Chairman of the Committee) presiding.

Present: Senators Kennedy, Weicker, Metzenbaum, Simon, Thurmond, and Adams.

OPENING STATEMENT OF SENATOR KENNEDY

The CHAIRMAN. We will come to order.

The AIDS epidemic is likely to continue to plague the nation well into the next decade and even into the next century. The number of people infected is staggering and it will continue to escalate.

The magnitude of this scourge, which has been called a possible catastrophe and a health disaster of pandemic proportion, may soon surpass any disease in this century and possibly any disease in history.

AIDS is a crisis for industrial and developing countries alike. We know that five to ten million people throughout the world are already infected, of whom one to two million live in the United States.

Within five years, there may be between 50 to 100 million people worldwide infected with the virus. Approximately five to ten million of them will be Americans. These unthinkable numbers and the equally alarming projections by the Public Health Service are convincing evidence that no sector of our society is safe from crisis.

Families, schools, businesses, recreational institutions, governments at every level are all being forced to confront the dilemmas, distress and even the hysteria provoked by AIDS.

From a local perspective, the number of cities and States with significant numbers of new cases increased at unprecedented levels over the last year. There are now 14 U.S. cities with more than 300 active cases of AIDS. There are 27 States with more than 100 active cases.

In five years, we will have approximately 270,000 people with active cases in the United States. Unless a cure is found, every one of these Americans will die. These numbers should convince us that all-out action is necessary. We must do as much as we can to halt the spread of AIDS and find the means to prevent it and cure it.

Over the past year, awareness and concern have increased dramatically in the Congress and throughout the country. A number of experts who are at the leading edge of the fight against AIDS are with us today as witnesses.

During 1986, several eminent institutions joined the effort to provide the leadership required to control and ultimately conquer this disease. Our witnesses this morning include the Surgeon General, the Co-Chairs of the National Academy of Science Panel on AIDS, the AIDS Coordinator of the World Health Organization and the National Institutes of Health, prominent representatives of industry, and distinguished researchers.

Most Americans were surprised to learn a few years ago that vaccine testing had already begun in the African country of Zaire. Some researchers have expressed concern about the nature of that vaccine and how it is being tested.

In this country, testing may begin within a year on one or possible additional AIDS vaccines. Yet, there are many questions which must be answered before a vaccine becomes safe, usable, and generally available.

Other questions are equally pressing. Are we moving drugs that offer the potential of a cure into clinical trials quickly enough? Is our national research effort large enough and targeted for maximum effectiveness?

In the meantime, those who are infected need compassion, support, and the hope of a cure. Those who are at risk of infection need counseling and education, and all of us need the commitment and the discipline to continue to give this crisis our highest priority and to provide resources and national leadership commensurate with that priority.

Lowell, do you want to make a statement?

Senator **Weicker**. Thank you very much, Mr. Chairman. I want to commend you for holding what I hope is one of many hearings in this Committee concerning Acquired Immune Deficiency Syndrome.

As AIDS continues to spread in epidemic proportions, it is essential to continually evaluate both the current battle against AIDS and the fight on behalf of the estimated 270,000 people who will have AIDS in 1991.

All of these efforts will cost money, and I was pleased to see the President did request some additional funding for AIDS research and other AIDS-related programs in his FY '88 budget.

However, while the President proposed a small increase for AIDS research, he also proposed a large cut in the funds for basic biomedical research. Such action reveals a total lack of understanding of what is needed to fight the diseases we know about and to be able to respond to new diseases that give us little or no warning before they appear.

I think most of my friends in the medical community would agree that the speed with which we identified and cloned the AIDS virus was due in large measure to the basic research funding that has preceded such discovery; that, indeed, it did not happen because all of a sudden we wanted to go ahead and discover the AIDS virus and pin all of our money and our hope on that. But because of a consistent, long-term funding for basic research, bio-medical research, we were able when the crisis hit to take care of that matter with alacrity.

Additional funding for AIDS is essential, but at the same time we must maintain the basic research efforts that make possible so much of what modern medical science can do. We cannot sacrifice one for the other; we need both.

The President talks so often about being prepared and building up budgets and arsenals in case there is a war. These preparations are made to fight against the possibility of danger to the Nation.

But with AIDS we know there are deaths and there will be more deaths. The Public Health Service estimates that by the end of 1991, there will have been a cumulative total of more than 179,000 deaths from AIDS in the United States, with 54,000 of those occurring in 1991 alone.

Thousands of people continue to die each year from cancer and heart disease and Alzheimer's, and yet the President would propose a retreat from the dollars that are most needed to find treatments and cures for those diseases.

In this hundredth anniversary year of the National Institutes of Health, the world's premiere center of health research, we must recognize NIH is also a vital outpost of national security. Assuring this security requires that research and treatment efforts be supported broadly.

No one would suggest the Nation needs only a navy or an army for the national defense and, likewise, the pluralistic efforts of health research in the Nation must be maintained.

Thank you, Mr. Chairman.

The CHAIRMAN. Thank you very much, Senator Weicker, for your comments.

We welcome the Assistant Secretary for Health, Mr. Windom, and we are glad to have him appear before our Committee, and the Surgeon General, to have him back before this Committee. He has produced a very excellent report on this issue previously and I think has really demonstrated very significant and important leadership for our country, and I commend you, Dr. Koop. We look forward to your testimony.

Dr. Windom.

STATEMENT OF ROBERT E. WINDOM, M.D., ASSISTANT SECRETARY FOR HEALTH, DEPARTMENT OF HEALTH AND HUMAN SERVICES, WASHINGTON, DC; AND C. EVERETT KOOP, M.D., SURGEON GENERAL, U.S. PUBLIC HEALTH SERVICE, WASHINGTON, DC

Dr. WINDOM. Thank you, Mr. Chairman, and Senator Weicker. We appreciate this opportunity to appear before you today to update you on our information and education initiatives to prevent and control the spread of AIDS.

The war on this devastating disease continues to be the Department's number one health priority. I am pleased to announce that the President's fiscal year 1988 budget contains a 28-percent increase for Public Health Service AIDS activities, bringing the total to slightly more than half a billion dollars.

To date, more than 29,000 AIDS cases have been reported in this country, with some 16,500 deaths. We estimate that 1 to 1.5 million more Americans are infected by the AIDS virus and can spread it to others even though they may currently show no signs of disease.

Present data indicate that at least 20 to 30 percent of these persons can be expected to develop AIDS itself within the next five years.

Heartening, indeed unprecedented progress has been made in research on AIDS, including identification of the AIDS virus, ensuring protection of the blood supply and hemophiliacs, identification of drugs of promise and initiation of clinical trials, and development of public health guidelines. Still, we have no cure, and general availability of an effective AIDS vaccine is still some years in the future.

AIDS, it is clear, will remain a serious problem for the Nation for years to come. Indeed, in June 1986, the report of the Public Health Service Coolfont Planning Conference projected that by the end of 1991, the total of AIDS cases will have exceeded 270,000, with more than 179,000 deaths.

In the absence of a cure or a vaccine, our best hopes today for stemming the spread of AIDS lie in ensuring that all Americans know the ways the AIDS virus is transmitted and the practical steps that they can take to protect themselves or, if they are already infected, to avoid spreading the virus to others.

From the beginning of the AIDS epidemic, as fast as knowledge about the disease was generated, the Public Health Service, in collaboration with non-federal experts and community leaders, developed and disseminated guidelines on AIDS to health professionals and the public.

Indeed, the 22 sets of Public Health Service guidelines that have been issued to date have formed a basis of AIDS information and education efforts in both the public and private sectors. Through grants, cooperative agreements and technical assistance, the Public Health Service has helped initiate and strengthen AIDS information, health education, and risk reduction programs in States, cities and local communities.

The Public Health Service toll-free AIDS hotline, which has been in operation since July of 1983, provides 24-hour-a-day service to callers from all over the Nation when they dial 1-800-342-AIDS.

The Public Health Service has also prepared and disseminated a variety of AIDS videotapes, fact sheets, pamphlets, and other materials targeted to population groups at special risk of infection, and to health care workers, emergency personnel, and the general public.

PHS is currently cooperating with the American Red Cross in a mass media campaign on AIDS that includes public service announcements, AIDS leaflets and posters.

Among other efforts, PHS has sponsored numerous national and regional conferences and workshops on AIDS to provide needed information about the disease to health care workers and State and local health officials.

The agency also sponsored the first International Conference on AIDS in April of 1985, cosponsored the second International Conference in June of 1986, and will sponsor the third, to be held here in Washington this coming June.

During the current fiscal year, PHS is devoting $79.5 million to AIDS information, education and risk reduction programs, and the President's budget proposes increasing this amount to $104 million in fiscal year 1988.

This year, PHS is implementing a detailed and comprehensive new public information and education plan, incorporating initiatives to be carried out by all relevant Public Health Service agencies. The Centers for Disease Control had the lead responsibility within PHS for carrying out this plan.

Under the plan, the Public Health Service will continue and expand the activities I have already outlined, and will undertake important new projects that are being developed. Efforts will target all segments of the general public—school and college-age Americans who represent the potential next generation of AIDS victims, persons now infected or at increased risk of infection, and health care providers.

Supplementing this plan are the efforts of the Alcohol, Drug Abuse, and Mental Health Administration to prevent the spread of AIDS among intravenous drugs abusers. AIDS infection among IV drug abusers represents a primary source of spread to heterosexuals, leading to perinatal infection and serving as a particular problem for minority populations.

Successful execution of the PHS plan will require action from and cooperation among State, county and municipal governments, professional and service organizations, the private sector, and other departments of the federal government.

We expect that non-federal entities, applying their own resources and ingenuity, will build upon and further disseminate the materials and information developed through federal dollars, thereby creating a multiplier effect.

An important boost to AIDS information efforts was provided last October by publication of the Public Health Service Surgeon General's Report on AIDS to the American public. The Public Health Service has undertaken extensive dissemination of this report, which has also been reprinted in full in a number of outside publications.

I want to take this opportunity to introduce to you Dr. C. Everett Koop, who gave that report and who works with us in our Public Health Service, as we lead this effort on AIDS education. Having just recovered from very serious surgery, he is back in full duty again.

The CHAIRMAN. Dr. Koop.

Dr. KOOP. Mr. Chairman, in February of 1986 during a visit to the Department of Health and Human Services, President Reagan asked me to report to him and to the American people on just what the AIDS threat was all about.

Although the United States Public Health Service and other public and private organizations had been disseminating current and accurate information about AIDS, there was still much misinformation circulating about the disease and the people at high risk.

The greatest human fear is fear of the unknown. Therefore, the President directed me to lay before the American people everything that was known, and to do that in plain English.

From that day on, barely a day went by over the next eight months that I was not involved in that assignment in some way. I was sure that an objective report on the health and medical aspects of AIDS could be produced, despite the presence of many sensitive and controversial issues.

I also consciously tried to make sure that the Surgeon General's Report on AIDS did not merely reflect my own or any single person's values, opinions or prejudices. To that end, I made the maximum possible effort to secure the advice and counsel from a broad spectrum of concerned individuals and organizations.

I consulted with the best medical and scientific experts available from within and outside the government, but I also met with leaders of many organizations concerned with the health, education and social well-being of the American people. I wanted to hear what they, too, had to say about the threat of the AIDS virus.

The response to my requests, I think, has been nothing short of extraordinary. For example, Mrs. Ann Kahn, the President of the National Parent Teachers Association, wrote to tell me that she and her colleagues benefited greatly from our meeting, and went on to say that she would be happy to share a copy of our report with 25,000 local PTA units.

And then President Mary Hatwood Futrell of the National Education Association told me she had ordered 3,000 copies of the report for distribution to national education leaders.

After I met with Larry Braidfoot and his colleagues from the Christian Life Commission of the Southern Baptist Convention, the largest Protestant denomination, he said the meeting had been very helpful in catalyzing within their group a focus for a growing concern about the problem and its threat to our society and its families.

Finally, after a joint consultation on AIDS with the Synagogue Council of America, Rabbi Henry Michelman assured me that the Council wished to cooperate with me in every way possible.

Those are just a few examples, Mr. Chairman, that I could offer, but I have attached to the concluding page of my statement a list of all 26 organizations with which I worked.

Finally, when it came to the actual writing, for which I personally take full responsibility, I tried to be as sensitive as possible to certain feelings that had been shared with me by many of those same individuals and organizations, yet not be so sensitive as to prejudice the objective information in any way.

Thanks to the contribution of many, I was able to produce a report which I believe reflects a wide range of experience with this disease and with many of the key issues that surround it.

It presents in plain English all the most up-to-date, pertinent and factual information that the American people need to protect themselves and their loved ones from the spread of AIDS.

I finished the manuscript this past September. I presented it to the Health Work Group of the White House and to the Cabinet Council on Domestic Policy, and they accepted my report without change and sent it on to the President, and I would like to submit a copy of this for the record, sir.

[The following material was received for the record:]

Surgeon
General's
Report
on

ACQUIRED IMMUNE DEFICIENCY SYNDROME

U.S. Department of Health
and Human Services

Foreword

This is a report from the Surgeon General of the U.S. Public Health Service to the people of the United States on AIDS. Acquired Immune Deficiency Syndrome is an epidemic that has already killed thousands of people, mostly young, productive Americans. In addition to illness, disability, and death, AIDS has brought fear to the hearts of most Americans – fear of disease and fear of the unknown. Initial reporting of AIDS occurred in the United States, but AIDS and the spread of the AIDS virus is an international problem. This report focuses on prevention that could be applied in all countries.

My report will inform you about AIDS, how it is transmitted, the relative risks of infection and how to prevent it. It will help you understand your fears. Fear can be useful when it helps people avoid behavior that puts them at risk for AIDS. On the other hand, unreasonable fear can be as crippling as the disease itself. If you are participating in activities that could expose you to the AIDS virus, this report could save your life.

In preparing this report, I consulted with the best medical and scientific experts this country can offer. I met with leaders of organizations concerned with health, education, and other aspects of our society to gain their views of the problems associated with AIDS. The information in this report is current and timely.

This report was written personally by me to provide the necessary understanding of AIDS.

The vast majority of Americans are against illicit drugs. As a health officer I am opposed to the use of illicit drugs. As a practicing physician for more than forty years, I have seen the devastation that follows the use of illicit drugs – addiction, poor health, family disruption, emotional disturbances and death. I applaud the President's initiative to rid this nation of the curse of illicit drug use and addiction. The success of his initiative is critical to the health of the American people and will also help reduce the number of persons exposed to the AIDS virus.

Some Americans have difficulties in dealing with the subjects of sex, sexual practices, and alternate lifestyles. Many Americans are opposed to homosexuality, promiscuity of any kind, and prostitution. This report must deal with all of these issues, but does so with the intent that information and education can change individual behavior, since this is the primary way to stop the epidemic of AIDS. This report deals with the positive and negative consequences of activities and behaviors from a health and medical point of view.

Adolescents and pre-adolescents are those whose behavior we wish to especially influence because of their vulnerability when they are exploring their own sexuality (heterosexual and homosexual) and perhaps experimenting with drugs. Teenagers often consider themselves immortal, and these young people may be putting themselves at great risk.

Education about AIDS should start in early elementary school and at home so that children can grow up knowing the behavior to avoid to protect themselves from exposure to the AIDS virus. The threat of AIDS can provide an opportunity for parents to instill in their children their own moral and ethical standards.

Those of us who are parents, educators and community leaders, indeed all adults, cannot disregard this responsibility to educate our young. The need is critical and the price of neglect is high. The lives of our young people depend on our fulfilling our responsibility.

AIDS is an infectious disease. It is contagious, but it cannot be spread in the same manner as a common cold or measles or chicken pox. It is contagious in the same way that sexually transmitted diseases, such as syphilis and gonorrhea, are contagious. AIDS can also be spread through the sharing of intravenous drug needles and syringes used for injecting illicit drugs.

AIDS is *not* spread by common everyday contact but by sexual contact (penis-vagina, penis-rectum, mouth-rectum, mouth-vagina, mouth-penis). Yet there is great misunderstanding resulting in unfounded fear that AIDS can be spread by casual, non-sexual contact. The first cases of AIDS were reported in this country in 1981. We would know by now if AIDS were passed by casual, non-sexual contact.

Today those practicing high-risk behavior who become infected with the AIDS virus are found mainly among homosexual and bisexual men and male and female intravenous drug users. Heterosexual transmission is expected to account for an increasing proportion of those who become infected with the AIDS virus in the future.

At the beginning of the AIDS epidemic many Americans had little sympathy for people with AIDS. The feeling was that somehow people from certain groups "deserved" their illness. Let us put those feelings behind us. We are fighting a disease, not people. Those who are already afflicted are sick people and need our care as do all sick patients. The country must face this epidemic as a unified society. We must prevent the spread of AIDS while at the same time preserving our humanity and intimacy.

AIDS is a life-threatening disease and a major public health issue. Its impact on our society is and will continue to be devastating. By the end of 1991, an estimated 270,000 cases of AIDS will have occurred with 179,000 deaths within the decade since the disease was first recognized. In the year 1991, an estimated 145,000 patients with AIDS will need health and supportive services at a total cost of between $8 and $16 billion. However, AIDS is preventable. It can be controlled by changes in personal behavior. It is the responsibility of every citizen to be informed about AIDS and to exercise the appropriate preventive measures. This report will tell you how.

The spread of AIDS can and must be stopped.

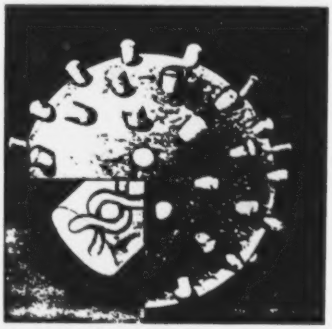
C Everett Koop

C. Everett Koop, M.D., Sc.D.
Surgeon General

AIDS

AIDS Caused by Virus

The letters A-I-D-S stand for Acquired Immune Deficiency Syndrome. When a person is sick with AIDS, he/she is in the final stages of a series of health problems caused by a virus (germ) that can be passed from one person to another chiefly during sexual contact or through the sharing of intravenous drug needles and syringes used for "shooting" drugs. Scientists have named the AIDS virus "HIV or HTLV-III or LAV"[1]. These abbreviations stand for information denoting a virus that attacks white blood cells (T-Lymphocytes) in the human blood. Throughout this publication, we will call the virus the "AIDS virus." The



Artist's drawing of AIDS virus with cut away view showing genetic (reproductive) material

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[1] These are different names given to AIDS virus by the scientific community:

HIV — Human Immunodeficiency Virus
HTLV-III — Human T-Lymphotropic Virus Type III
LAV — Lymphadenopathy Associated Virus

AIDS virus attacks a person's immune system and damages his/her ability to fight other disease. Without a functioning immune system to ward off other germs, he/she now becomes vulnerable to becoming infected by bacteria, protozoa, fungi, and other viruses and malignancies, which may cause life threatening illness, such as pneumonia, meningitis, and cancer.

No Known Cure

There is presently no cure for AIDS. There is presently no vaccine to prevent AIDS.

Virus Invades Blood Stream

When the AIDS virus enters the blood stream, it begins to attack certain white blood cells (T Lymphocytes). Substances called antibodies are produced by the body. These antibodies can be detected in the blood by a simple test, usually two weeks to three months after infection. Even before the antibody test is positive, the victim can pass the virus to others by methods that will be explained.

Once an individual is infected, there are several possibilities. Some people may remain well but even so they are able to infect others. Others may develop a disease that is less serious than AIDS referred to as AIDS Related Complex (ARC). In some people the protective immune system may be destroyed by the virus and then other germs (bacteria, protozoa, fungi and other viruses) and cancers that ordinarily would never get a foothold cause "opportunistic diseases" — using the *opportunity* of lowered resistance to infect and destroy. Some of the most common are *Pneumocystis carinii* pneumonia and tuberculosis. Individuals infected with the AIDS virus may also develop certain types of cancers such as Kaposi's sarcoma. These infected people have classic AIDS. Evidence shows that the AIDS virus may also attack the nervous system, causing damage to the brain.

Signs and Symptoms

No Signs

Some people remain apparently well after infection with the AIDS virus. They may have no physically apparent symptoms of illness. However, if proper precautions are not used with sexual contacts and/or intravenous drug use, these infected individuals can spread the virus to others. Anyone who thinks he or she is infected or involved in high risk behaviors should not donate his/her blood, organs, tissues, or sperm because they may now contain the AIDS virus.

ARC

AIDS Related Complex (ARC) is a condition caused by the AIDS virus in which the patient tests positive for AIDS infection and has a specific set of clinical symptoms. However, ARC patients' symptoms are often less severe than those with the disease we call classic AIDS. Signs and symptoms of ARC may include loss of appetite, weight loss, fever, night sweats, skin rashes, diarrhea, tiredness, lack of resistance to infection, or swollen lymph nodes. These are also signs and symptoms of many other diseases and a physician should be consulted.

AIDS

Only a qualified health professional can diagnose AIDS, which is the result of a natural progress of infection by the AIDS virus. AIDS destroys the body's immune (defense) system and allows otherwise controllable infections to invade the body and cause additional diseases. These opportunistic diseases would not otherwise gain a foothold in the body. These opportunistic diseases may eventually cause death.

Some symptoms and signs of AIDS and the "opportunistic infections" may include a persistent cough and fever associated with shortness of breath or difficult breathing and may be the symptoms of *Pneumocystis carinii* pneumonia. Multiple purplish blotches and bumps on the skin may be a sign of Kaposi's sarcoma. The AIDS virus in all infected people is essentially the same; the reactions of individuals may differ.

Long Term

The AIDS virus may also attack the nervous system and cause delayed damage to the brain. This damage may take years to develop and the symptoms may show up as memory loss, indifference, loss of coordination, partial paralysis, or mental disorder. These symptoms may occur alone, or with other symptoms mentioned earlier.

AIDS: the present situation

The number of people estimated to be infected with the AIDS virus in the United States is about 1.5 million. All of these individuals are assumed to be capable of spreading the virus sexually (heterosexually or homosexually) or by sharing needles and syringes or other implements for intravenous drug use. Of these, an estimated 100,000 to 200,000 will come down with AIDS Related Complex (ARC). It is difficult to predict the number who will develop ARC or AIDS because symptoms sometimes take as long as nine years to show up. With our present knowledge, scientists predict that 20 to 30 percent of those infected with the AIDS virus will develop an illness that fits an accepted definition of AIDS within five years. The number of persons known to have AIDS in the United States to date is over 25,000; of these, about half have died of the disease. Since there is no cure, the others are expected to also eventually die from their disease.

The majority of infected antibody positive individuals who carry the AIDS virus show no disease symptoms and may not come down with the disease for many years, if ever.

No Risk from Casual Contact

There is no known risk of non-sexual infection in most of the situations we encounter in our daily lives. We know that family members living with individuals who have the AIDS virus do not become infected except through sexual contact. There is no evidence of transmission (spread) of AIDS virus by everyday contact even though these family members shared food, towels, cups, razors, even toothbrushes, and kissed each other.

Health Workers

We know even more about health care workers exposed to AIDS patients. About [illegible]500 health workers who were caring for AIDS patients when they were sickest have been carefully studied and tested for infection with the AIDS virus. These doctors, nurses and other health care givers have been exposed to the AIDS patients' blood, stool and other body fluids. Approximately 750 of these health workers reported possible additional exposure by direct contact with a patient's body fluid through spills or being accidentally stuck with a needle. Upon testing these 750, only 3 who had accidentally stuck themselves with a needle had a positive antibody test for exposure to the AIDS virus. Because health workers had much more contact with patients and their body fluids than would be expected from common everyday contact, it is clear that the AIDS virus is not transmitted by casual contact.

Control of Certain Behaviors Can Stop Further Spread of AIDS

Knowing the facts about AIDS can prevent the spread of the disease. Education of those who risk infecting themselves or infecting other people is the only way we can stop the spread of AIDS. People must be responsible about their sexual behavior and must avoid the use of illicit intravenous drugs and needle sharing. We will describe the types of behavior that lead to infection by the AIDS virus and the personal measures that must be taken for effective protection. If we are to stop the AIDS epidemic, we all must understand the disease – its cause, its nature, and its prevention. *Precautions must be taken.* The AIDS virus infects persons who expose themselves to known risk behavior, such as certain types of homosexual and heterosexual activities or sharing intravenous drug equipment.

Risks

Although the initial discovery was in the homosexual community, AIDS is not a disease only of homosexuals. AIDS is found in heterosexual people as well. AIDS is not a black or white disease. AIDS is not just a male disease. AIDS is found in women; it is found in children. In the future AIDS will probably increase and spread among people who are not homosexual or intravenous drug abusers in the same manner as other sexually transmitted diseases like syphilis and gonorrhea.

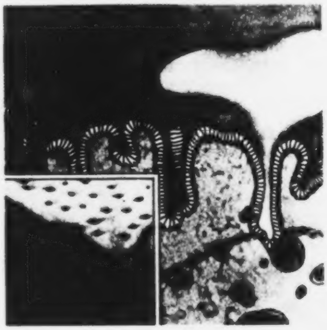
Sex Between Men

Men who have sexual relations with other men are especially at risk. About 70 percent of AIDS victims throughout the country are male homosexuals and bisexuals. This percentage probably will decline as heterosexual transmission increases. *Infection results from a sexual relationship with an infected person.*

Multiple Partners

The risk of infection increases according to the number of sexual partners one has, *male or female*. The more partners you have, the greater the risk of becoming infected with the AIDS virus.

Vulnerable rectum lining provides avenue for entry of AIDS virus into the blood stream.



How Exposed

Although the AIDS virus is found in several body fluids, a person acquires the virus during sexual contact with an infected person's blood or semen and possibly vaginal secretions. The virus then enters a person's blood stream through their rectum, vagina or penis.

Small (unseen by the naked eye) tears in the surface lining of the vagina or rectum may occur during insertion of the penis, fingers, or other objects, thus opening an avenue for entrance of the virus directly into the blood stream; therefore, the AIDS virus can be passed from penis to rectum and vagina and vice versa without a visible tear in the tissue or the presence of blood.

Prevention of Sexual Transmission – Know Your Partner

Couples who maintain mutually faithful monogamous relationships (only one continuing sexual partner) are protected from AIDS through sexual transmission. If you have been faithful for at least five years and your partner has been faithful too, neither of you is at risk. If you have not been faithful, then you and your partner are at risk. If your partner has not been faithful, then your partner is at risk which also puts you at risk. This is true for both heterosexual and homosexual couples. Unless it is possible to know with *absolute certainty* that neither you nor your sexual partner is carrying the virus of AIDS, you must use protective behavior. *Absolute certainty* means not only that you and your partner have maintained a mutually faithful monogamous sexual relationship, but it means that neither you nor your partner has used illegal intravenous drugs.

AIDS: you can protect yourself from infection

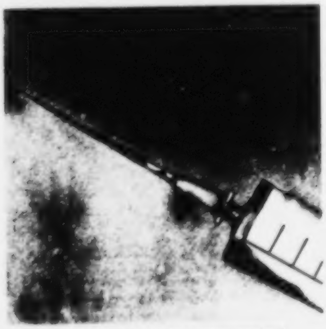
Some personal measures are adequate to safely protect yourself and others from infection by the AIDS virus and its complications. Among these are:

- If you have been involved in any of the high risk sexual activities described above or have injected illicit intravenous drugs into your body, you should have a blood test to see if you have been infected with the AIDS virus.
- If your test is positive or if you engage in high risk activities and choose not to have a test, you should tell your sexual partner. If you jointly decide to have sex, you must protect your partner by always using a rubber (condom) during (start to finish) sexual intercourse (vagina or rectum).

AZTECS
ONE ROLLED LATEX CONDOM

- If your partner has a positive blood test showing that he/she has been infected with the AIDS virus or you suspect that he/she has been exposed by previous heterosexual or homosexual behavior or use of intravenous drugs with shared needles and syringes, a rubber (condom) should always be used during (start to finish) sexual intercourse (vagina or rectum).

- If you or your partner is at high risk, avoid mouth contact with the penis, vagina, or rectum.
- Avoid all sexual activities which could cause cuts or tears in the linings of the rectum, vagina, or penis.
- Single teen age girls have been warned that pregnancy and contracting sexually transmitted diseases can be the result of only one act of sexual intercourse. They have been taught to say *NO* to sex! They have been taught to say *NO* to drugs! By saying *NO* to sex and drugs, they can avoid AIDS which can ***kill*** them! The same is true for teenage boys who should also not have rectal intercourse with other males. It may result in AIDS.
- Do not have sex with prostitutes. Infected male and female prostitutes are frequently also intravenous drug abusers, therefore, they may infect clients by sexual inter course and other intravenous drug abusers by sharing their intravenous drug equipment. Female prostitutes also can infect their unborn babies.



Dirty intravenous needle and syringe contaminated with blood that may contain the AIDS virus.

Intravenous Drug Users

Drug abusers who inject drugs into their veins are another population group at high risk and with high rates of infec tion by the AIDS virus. Users of intravenous drugs make up 25 percent of the cases of AIDS throughout the country. The AIDS virus is carried in contaminated blood left in the needle, syringe, or other drug related implements and the virus is injected into the new victim by reusing dirty syringes and needles. Even the smallest amount of infected blood left in a used needle or syringe can contain live AIDS virus to be passed on to the next user of those dirty implements.

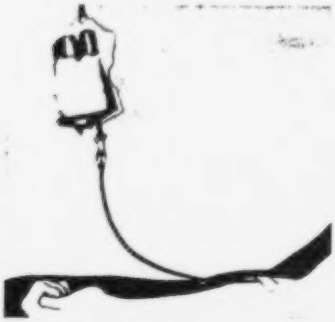
No one should shoot up drugs because addiction, poor health, family disruption, emotional disturbances and death could follow. However, many drug users are addicted to drugs and for one reason or another have not changed their behavior. For these people, the only way not to get AIDS is *to use a clean, previously unused* needle, syringe or any other implement necessary for the injection of the drug solution.

Hemophilia

Some persons with hemophilia (a blood clotting disorder that makes them subject to bleeding) have been infected with the AIDS virus either through blood transfusion or the use of blood products that help their blood clot. Now that we know how to prepare safe blood products to aid clotting, this is unlikely to happen. This group represents a very small percentage of the cases of AIDS throughout the country.

Blood Transfusion

Currently all blood donors are initially screened and blood is *not* accepted from high risk individuals. Blood that has been collected for use is tested for the presence of antibody to the AIDS virus. However, some people may have had a blood transfusion prior to March 1985 before we knew how to screen blood for safe transfusion and may have become



infected with the AIDS virus. Fortunately there are not now a large number of these cases. With routine testing of blood products, the blood supply for transfusion is now safer than it has ever been with regard to AIDS.

Persons who have engaged in homosexual activities or have shot street drugs within the last 10 years should *never* donate blood.

Mother Can Infect Newborn

If a woman is infected with the AIDS virus and becomes pregnant, she is more likely to develop ARC or classic AIDS, and she can pass the AIDS virus to her unborn child. Approximately one third of the babies born to AIDS-infected mothers will also be infected with the AIDS virus. Most of the infected babies will eventually develop the disease and die. Several of these babies have been born to wives of hemophiliac men infected with the AIDS virus by way of contaminated blood products. Some babies have also been born to women who became infected with the AIDS virus by bisexual partners who had the virus. Almost all babies with AIDS have been born to women who were intravenous

drug users or the sexual partners of intravenous drug users who were infected with the AIDS virus. More such babies can be expected.

Think carefully if you plan on becoming pregnant. If there is any chance that you may be in any high risk group or that you have had sex with someone in a high risk group, such as homosexual and bisexual males, drug abusers and their sexual partners, see your doctor.

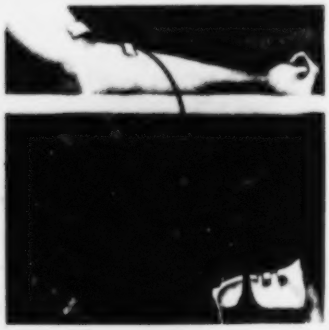
Summary

AIDS affects certain groups of the population. Homosexual and bisexual males who have had sexual contact with other homosexual or bisexual males as well as those who "shoot" street drugs are at greatest risk of exposure, infection and eventual death. Sexual partners of these high risk individuals are at risk, as well as any children born to women who carry the virus. Heterosexual persons are increasingly at risk.

AIDS: what is safe

Most Behavior is Safe

Everyday living does not present any risk of infection. You *cannot* get AIDS from casual social contact. Casual social contact should not be confused with casual *sexual* contact which is a major cause of the spread of the AIDS virus. Casual *social* contact such as shaking hands, hugging, social kissing, crying, coughing or sneezing, will not transmit the AIDS virus. Nor has AIDS been contracted from swimming in pools or bathing in hot tubs or from eating in restaurants (even if a restaurant worker has AIDS or carries the AIDS virus.) AIDS is not contracted from sharing bed linens, towels, cups, straws, dishes, or any other eating utensils. You cannot get AIDS from toilets, doorknobs, telephones, office machinery, or household furniture. You cannot get AIDS from body massages, masturbation or any non-sexual contact.



Donating Blood

Donating blood is *not* risky at all. *You cannot get AIDS by donating blood.*

Receiving Blood

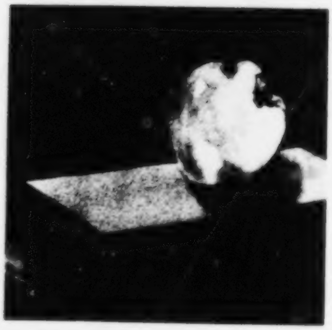
In the U.S. every blood donor is screened to exclude high risk persons and every blood donation is now tested for the presence of antibodies to the AIDS virus. Blood that shows exposure to the AIDS virus by the presence of antibodies is not used either for transfusion or for the manufacture of blood products. Blood banks are as safe as current technology can make them. Because antibodies do not form immediately after exposure to the virus, a newly infected person may unknowingly donate blood after becoming infected but before his/her antibody test becomes positive. It is estimated that this might occur less than once in 100,000 donations.

There is no danger of AIDS virus infection from visiting a doctor, dentist, hospital, hairdresser or beautician. AIDS cannot be transmitted non sexually from an infected person through a health or service provider to another person. Ordinary methods of disinfection for urine, stool and vomitus which are used for non infected people are adequate for people who have AIDS or are carrying the AIDS virus. You may have wondered why your dentist wears gloves and perhaps a mask when treating you. This does not mean that he has AIDS or that he thinks you do. He is protecting you and himself from hepatitis, common colds or flu.

There is no danger in visiting a patient with AIDS or caring for him or her. Normal hygienic practices, like wiping of body fluid spills with a solution of water and household bleach (1 part household bleach to 10 parts water), will provide full protection.

Children in School

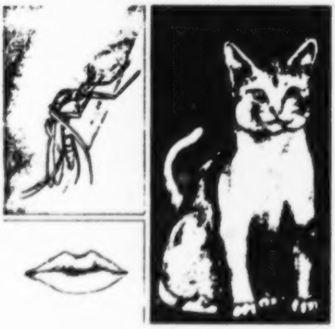
None of the identified cases of AIDS in the United States are known or are suspected to have been transmitted from one child to another in school, day care, or foster care settings. Transmission would necessitate exposure of open



cuts to the blood or other body fluids of the infected child, a highly unlikely occurrence. Even then routine safety procedures for handling blood or other body fluids (which should be standard for all children in the school or day care setting) would be effective in preventing transmission from children with AIDS to other children in school.

Children with AIDS are highly susceptible to infections, such as chicken pox, from other children. Each child with AIDS should be examined by a doctor before attending school or before returning to school, day care or foster care settings after an illness. No blanket rules can be made for all school boards to cover all possible cases of children with AIDS and each case should be considered separately and individualized to the child and the setting, as would be done with any child with a special problem, such as cerebral palsy or asthma. A good team to make such decisions with the school board would be the child's parents, physician and a public health official.

Casual social contact between children and persons infected with the AIDS virus is not dangerous.



Insects

There are no known cases of AIDS transmission by insects, such as mosquitoes.

Pets

Dogs, cats and domestic animals are not a source of infection from AIDS virus.

Tears and Saliva

Although the AIDS virus has been found in tears and saliva, no instance of transmission from these body fluids has been reported.

AIDS comes from sexual contacts with infected persons and from the sharing of syringes and needles. There is no danger of infection with AIDS virus by casual social contact.

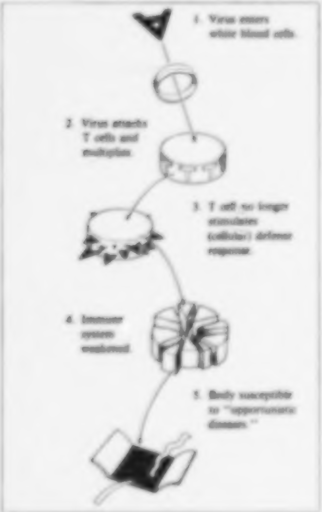
Testing of Military Personnel

You may wonder why the Department of Defense is currently testing its uniformed services personnel for presence of the AIDS virus antibody. The military feel this procedure is necessary because the uniformed services act as their own blood bank in a time of national emergency. They also need to protect new recruits (who unknowingly may be AIDS virus carriers) from receiving live virus vaccines. These vaccines could activate disease and be potentially life-threatening to the recruits.

AIDS: what is currently understood

Although AIDS is still a mysterious disease in many ways, our scientists have learned a great deal about it. In five years we know more about AIDS than many diseases that we have studied for even longer periods. While there is no vaccine or cure, the results from the health and behavioral research community can only add to our knowledge and increase our understanding of the disease and ways to prevent and treat it.

In spite of all that is known about transmission of the AIDS virus, scientists will learn more. One possibility is the potential discovery of factors that may better explain the mechanism of AIDS infection.


1. Virus enters white blood cells.
2. Virus attacks T cells and multiplies.
3. T cell no longer stimulates (cellular) defense response.
4. Immune system weakened.
5. Body susceptible to "opportunistic diseases."

Why are the antibodies produced by the body to fight the AIDS virus not able to destroy that virus?

The antibodies detected in the blood of carriers of the AIDS virus are ineffective, at least when classic AIDS is actually triggered. They cannot check the damage caused by the virus, which is by then present in large numbers in the body. Researchers cannot explain this important observation. We still do not know why the AIDS virus is not destroyed by man's immune system.

Summary

AIDS no longer is the concern of any one segment of society; it is the concern of us all. No American's life is in danger if he/she or their sexual partners do not engage in high risk sexual behavior or use shared needles or syringes to inject illicit drugs into the body.

People who engage in high risk sexual behavior or who shoot drugs are risking infection with the AIDS virus and are risking their lives and the lives of others, including their unborn children.

We cannot yet know the full impact of AIDS on our society. From a clinical point of view, there may be new manifestations of AIDS—for example, mental disturbances due to the infection of the brain by the AIDS virus in carriers of the virus. From a social point of view, it may bring to an end the free-wheeling sexual lifestyle which has been called the sexual revolution. Economically, the care of AIDS patients will put a tremendous strain on our already overburdened and costly health care delivery system.

The most certain way to avoid getting the AIDS virus and to control the AIDS epidemic in the United States is for individuals to avoid promiscuous sexual practices, to maintain mutually faithful monogamous sexual relationships and to avoid injecting illicit drugs.

Look to the Future

The Challenge of the Future

An enormous challenge to public health lies ahead of us and we would do well to take a look at the future. We must be prepared to manage those things we can predict, as well as those we cannot.

At the present time there is no vaccine to prevent AIDS. There is no cure. AIDS, which can be transmitted sexually and by sharing needles and syringes among illicit intravenous drug users, is bound to produce profound changes in our society, changes that will affect us all.

Information and Education Only Weapons Against AIDS

It is estimated that in 1991 54,000 people will die from AIDS. At this moment, many of them are not infected with the AIDS virus. With proper information and education, as many as 12,000 to 14,000 people could be saved in 1991 from death by AIDS.

AIDS will Impact All

The changes in our society will be economic and political and will affect our social institutions, our educational practices, and our health care. Although AIDS may never touch you personally, the societal impact certainly will.

Be Educated - Be Prepared

Be prepared. Learn as much about AIDS as you can. Learn to separate scientific information from rumor and myth. The Public Health Service, your local public health officials and your family physician will be able to help you.

Concern About Spread of AIDS

While the concentration of AIDS cases is in the larger urban areas today, it has been found in every state and with the mobility of our society, it is likely that cases of AIDS will appear far and wide.

Special Educational Concerns

There are a number of people, primarily adolescents, that do not yet know they will be homosexual or become drug abusers and will not heed this message; there are others who are illiterate and cannot heed this message. They must be reached and taught the risk behaviors that expose them to infection with the AIDS virus.

High Risk Get Blood Test

The greatest public health problem lies in the large number of individuals with a history of high risk behavior who have been infected with and may be spreading the AIDS virus. Those with high risk behavior must be encouraged to protect others by adopting safe sexual practices and by the use of clean equipment for intravenous drug use. If a blood test for antibodies to the AIDS virus is necessary to get these individuals to use safe sexual practices, they should get a blood test. Call your local health department for information on where to get the test.

Anger and Guilt

Some people afflicted with AIDS will feel a sense of anger and others a sense of guilt. In spite of these understandable reactions, everyone must join the effort to control the epidemic, to provide for the care of those with AIDS, and to do all we can to inform and educate others about AIDS, and how to prevent it.

Confidentiality

Because of the stigma that has been associated with AIDS, many afflicted with the disease or who are infected with the AIDS virus are reluctant to be identified with AIDS. Because there is no vaccine to prevent AIDS and no cure, many feel there is nothing to be gained by revealing sexual contacts that might also be infected with the AIDS virus. When a community or a state requires reporting of those infected with the AIDS virus to public health authorities in order to trace sexual and intravenous drug contacts — as is the practice with other sexually transmitted diseases — those infected with the AIDS virus go underground out of the mainstream of health care and education. For this reason current public health practice is to protect the privacy of the individual infected with the AIDS virus and to maintain the strictest confidentiality concerning his/her health records.

State and Local AIDS Task Forces

Many state and local jurisdictions where AIDS has been seen in the greatest numbers have AIDS task forces with heavy representation from the field of public health joined by others who can speak broadly to issues of access to care, provision of care and the availability of community and psychiatric support services. Such a task force is needed in every community with the power to develop plans and policies, to speak, and to act for the good of the public health at every level.

State and local task forces should plan ahead and work collaboratively with other jurisdictions to reduce transmission of AIDS by far-reaching informational and educational programs. As AIDS impacts more strongly on society, they should be charged with making recommendations to provide for the needs of those afflicted with AIDS. They also will be in the best position to answer the concerns and direct the activities of those who are not infected with the AIDS virus.

The responsibility of State and local task forces should be far reaching and might include the following areas:

- Insure enforcement of public health regulation of such practices as ear piercing and tattooing to prevent transmission of the AIDS virus.
- Conduct AIDS education programs for police, firemen, correctional institution workers and emergency medical personnel for dealing with AIDS victims and the public.
- Insure that institutions catering to children or adults who soil themselves or their surroundings with urine, stool, and vomitus have adequate equipment for cleanup and disposal, and have policies to insure the practice of good hygiene.

School

Schools will have special problems in the future. In addition to the guidelines already mentioned in this pamphlet, there are other things that should be considered such as sex education and education of the handicapped.

Sex Education

Education concerning AIDS must start at the lowest grade possible as part of any health and hygiene program. The appearance of AIDS could bring together diverse groups of parents and educators with opposing views on inclusion of sex education in the curricula. There is now no doubt that we need sex education in schools and that it must include information on heterosexual and homosexual relationships. The threat of AIDS should be sufficient to permit a sex education curriculum with a heavy emphasis on prevention of AIDS and other sexually transmitted diseases.

Handicapped and Special Education

Children with AIDS or ARC will be attending school along with others who carry the AIDS virus. Some children will develop brain disease which will produce changes in mental behavior. Because of the right to special education of the handicapped and the mentally retarded, school boards and higher authorities will have to provide guidelines for the management of such children on a case-by-case basis.

Labor and Management

Labor and management can do much to prepare for AIDS so that misinformation is kept to a minimum. Unions should issue preventive health messages because many employees will listen more carefully to a union message than they will to one from public health authorities.

AIDS Education at the Work Site

Offices, factories, and other work sites should have a plan in operation for education of the work force and accommodation of AIDS or ARC patients *before* the first such case appears at the work site. Employees with AIDS or ARC should be dealt with as are any workers with a chronic illness. In-house video programs provide an excellent source of education and can be individualized to the needs of a specific work group.

Strain on the Health Care Delivery System

The health care system in many places will be overburdened as it is now in urban areas with large numbers of AIDS patients. It is predicted that during 1991 there will be 145,000 patients requiring hospitalization at least once and 54,000 patients who will die of AIDS. Mental disease (dementia) will occur in some patients who have the AIDS virus before they have any other manifestation such as ARC or classic AIDS.

State and local task forces will have to plan for these patients by utilizing conventional and time honored systems but will also have to investigate alternate methods of treatment and alternate sites for care including homecare.

The strain on the health system can be lessened by family, social, and psychological support mechanisms in the community. Programs are needed to train chaplains, clergy, social workers, and volunteers to deal with AIDS. Such support is particularly critical to the minority communities.

Mental Health

Our society will also face an additional burden as we better understand the mental health implications of infection by the AIDS virus. Upon being informed of infection with the AIDS virus, a young, active, vigorous person faces anxiety and depression brought on by fears associated with social isolation, illness, and dying. Dealing with these individual and family concerns will require the best efforts of mental health professionals.

Controversial Issues

A number of controversial AIDS issues have arisen and will continue to be debated largely because of lack of knowledge about AIDS, how it is spread, and how it can be prevented. Among these are the issues of compulsory blood testing, quarantine, and identification of AIDS carriers by some visible sign.

Compulsory Blood Testing

Compulsory blood testing of individuals is not necessary. The procedure could be unmanageable and cost prohibitive. It can be expected that many who test negatively might actually be positive due to recent exposure to the AIDS virus and give a false sense of security to the individual and his/her sexual partners concerning necessary protective behavior. The prevention behavior described in this report, if adopted, will protect the American public and contain the AIDS epidemic. Voluntary testing will be available to those who have been involved in high risk behavior.

Quarantine

Quarantine has no role in the management of AIDS because AIDS is not spread by casual contact. The only time that some form of quarantine might be indicated is in a situation where an individual carrying the AIDS virus knowingly and willingly continues to expose others through sexual contact or sharing drug equipment. Such circumstances should be managed on a case-by-case basis by local authorities.

Identification of AIDS Carriers by Some Visible Sign

Those who suggest the marking of carriers of the AIDS virus by some visible sign have not thought the matter through thoroughly. It would require testing of the entire population which is unnecessary, unmanageable and costly. It would miss those recently infected individuals who would test negatively, but be infected. The entire procedure would give a false sense of security. AIDS must and will be treated as a disease that can infect anyone. AIDS should not be used as an excuse to discriminate against any group or individual.

Updating Information

As the Surgeon General, I will continually monitor the most current and accurate health, medical, and scientific information and make it available to you, the American people. Armed with this information you can join in the discussion and resolution of AIDS-related issues that are critical to your health, your children's health, and the health of the nation.

Additional Information

Telephone Hotlines (Toll Free)

PHS AIDS Hotline
800-342-AIDS
800-342-2437

National Sexually Transmitted Diseases Hotline
American Social Health Association
800-227-8922

National Gay Task Force
AIDS Information Hotline
800-221-7044
(212) 807-6016 (NY State)

Information Sources

U.S. Public Health Service
Public Affairs Office
Hubert H. Humphrey Building, Room 725-H
200 Independence Avenue, S.W.
Washington, D.C. 20201
Phone: (202) 245-6867

Local Red Cross or
American Red Cross
AIDS Education Office
1730 D Street, N.W.
Washington, D.C. 20006
Phone: (202) 737-8300

American Association of Physicians for Human Rights
P.O. Box 14366
San Francisco, CA 94114
Phone: (415) 558-9353

AIDS Action Council
729 Eighth Street, S.E.,
Suite 200
Washington, D.C. 20003
Phone: (202) 547-3101

Gay Men's Health Crisis
P.O. Box 274
132 West 24th Street
New York, NY 10011
Phone: (212) 807-6655

Hispanic AIDS Forum
c/o APRED
853 Broadway, Suite 2007
New York, NY 10003
Phone: (212) 870-1902 or 870-1864

Los Angeles AIDS Project
1362 Santa Monica Boulevard
Los Angeles, California 90046
(213) 871-AIDS

Minority Task Force on AIDS
c/o New York City Council
of Churches
475 Riverside Drive,
Room 456
New York, NY 10115
Phone: (212) 749-1214

Mothers of AIDS Patients
(MAP)
c/o Barbara Peabody
3403 E Street
San Diego, CA 92102
(619) 234-3432

National AIDS Network
729 Eighth Street, S.E.,
Suite 300
Washington D.C. 20003
(202) 546-2424

National Association of
People with AIDS
P.O. Box 65472
Washington, D.C. 20035
(202) 483-7979

National Coalition of Gay
Sexually Transmitted
Disease Services
c/o Mark Behar
P.O. Box 239
Milwaukee, WI 53201
Phone: (414) 277-7671

National Council of
Churches/AIDS Task Force
475 Riverside Drive,
Room 572
New York, NY 10115
Phone: (212) 870-2421

San Francisco AIDS
Foundation
333 Valencia Street,
4th Floor
San Francisco, CA 94103
Phone: (415) 863-2437

During the preparation of the *Surgeon General's Report on Acquired Immune Deficiency Syndrome*, Surgeon General C. Everett Koop, MD, met personally and privately with representatives of the following groups:

AIDS Advocacy Groups

AIDS Action Council
National Coalition of Black Lesbians and Gays
National Minority AIDS Council

Business

American Council on Life Insurance
Health Insurance Association of America
Washington Business Group on Health

Education

National Association of Elementary School Principals
National Association of Secondary School Principals
National Association of State Boards of Education
National Education Association
National Parents and Teachers Association

Health

American Dental Association
American Hospital Association
American Medical Association
American Nurses Association
American Osteopathic Association
American Red Cross
National Hemophilia Foundation

Labor

American Federation of Teachers
Service Employees International Union

Public Officials

Association of State and Territorial Health Officers
National Association of County Health Officials
U.S. Conference of Local Health Officers

Religion

Christian Life Council of the Southern Baptist Convention
National Council of Churches of Christ
Synagogue Council of America
U.S. Catholic Conference

Dr. Koop. I would like to emphasize, too, Mr. Chairman, that throughout this assignment I was accorded full independence to pursue the research and writing of my report in whatever manner I thought appropriate, and at no time did anyone try to exercise any undue influence on the outcome.

If I could give you just what I think are the three highlights of the report, they would be these. First, the risk of infection increases with increased numbers of sexual partners, male or female. Anyone who engages in free-wheeling, casual sex is playing a dangerous game.

Unless you know with absolute certainty that your sex partner has not become infected with the AIDS virus through sex or drug use, you are taking a chance on becoming infected.

Conversely, unless you are absolutely certain that you yourself are not carrying the AIDS virus, you must consider the possibility that you can infect others.

Second, the best protection against the infection right now, barring abstinence, is the use of a condom. A condom should be used during sexual relations from start to finish with anyone whom you are not absolutely sure is free of the AIDS virus.

And, third, we need to get the facts about this disease to every American. The Public Health Service has the responsibility to provide clear and accurate information about AIDS to all segments of our society. In particular, our youth must understand that sexual activity and IV drug use can lead to AIDS.

The Public Health Service will provide educators with requested factual and timely information about AIDS, but families, along with parent and community groups and State and local school boards, have the primary responsibility for educating the young.

These groups should determine how best to employ this information, with consideration of their own values, to achieve the goal of preventing AIDS among young people.

Mr. Chairman, I believe the threat of AIDS is serious enough to permit the kind of education that emphasizes the prevention of AIDS and other sexually-transmitted diseases. The need is critical and the price of neglect is high.

As part of our own education and information effort, we have already distributed 250,000 copies of the Surgeon General's Report on AIDS in answer to telephone and mail requests. And, in addition, such publications as the Journal of the American Medical Association and the Los Angeles Times have reprinted the report in full for their readers. And we have made camera-ready copies available to a number of national organizations who wish to do their own printing and distribution, and one of these has gone to every health officer of each of the 50 States.

The report has been copied elsewhere. For example, the governments of France and Australia have informed us that they intend to reprint and distribute the report among their own citizens.

With this kind of reception, Mr. Chairman, I believe the Surgeon General's Report on AIDS is having the salutary effect the President had hoped for not only here in the United States, but elsewhere in the world as well.

Thank you, Mr. Chairman. I would be pleased to answer questions.

The **Chairman**. Thank you very much, Dr. Koop. I think all of us who have followed this issue in the Congress and outside as well have to commend you for the leadership that you have been providing and the courage with which you have brought this to the attention of the American people.

I think that your presentations have been very clear. I would like to review a couple of the significant facts, because I understand that unless we find a cure for the disease, between 20 and 50 percent of those infected will eventually develop the full-blown disease. Is that correct?

Dr. **Koop**. That is correct. Because of the long incubation period, sir, it is absolutely impossible for anyone to tell you how many of those who have the virus and are now asymptomatic will come down with the classic AIDS syndrome or something less. Your figures are correct, but they could be higher.

The **Chairman**. And the disease so far has proven a hundred percent fatal, is that correct?

Dr. **Koop**. That is correct, sir.

The **Chairman**. And it is true, is it not, that unless we mount an aggressive campaign to control the spread of the disease, the number of infected Americans could climb as high as five million by 1991?

Dr. **Koop**. I think that is correct because we have neither a drug for cure nor a vaccine for prevention.

The **Chairman**. It seems that our best efforts are, one, the development of a vaccine, and second, the whole question of education. You have identified these goals in your report.

Now, your recommendations require support from all levels of government and the private sector. What do you think should be the role of the federal government in terms of the information campaign?

Dr. **Koop**. I think it is the obligation of the federal government, particularly the Public Health Service, to make available to the States, to the people, to the private sector, all of the information that we know scientifically and demonstrate to them our willingness to work with them in any way that we can, perhaps even set up cooperative demonstration projects.

But inasmuch as education and information are the only weapons we have against AIDS, it will require extreme cooperation, and we have to be innovative in the manner in which we do this because we are dealing with some people who are victims of this disease and are possible victims in the future who are not literate enough to follow a report such as we have written, and we have to reach those people as well.

The **Chairman**. Well, do you think the federal government role is adequate, given the nature of the crisis today?

Dr. **Koop**. I think it is, sir, and I think that we are gathering momentum; we are getting up more steam. We are working as hard as we can. We will be coming out with as much information as I think the public and the State and local health officers can absorb, and we will be standing behind them to help in way that we can.

The **Chairman**. Let me ask you, as a result of your own study and the material, the information that you had had available based upon scientific information, should the American people be concerned about catching the disease from casual contact?

Dr. **Koop**. No, sir. AIDS is not——

The **Chairman**. Let me—because we have people watching this and for the record, it is important. We are talking about in the workplace, we are talking about food service workers, or even from infected children in schools.

I would like to hear your answer and I want you to tell us what is the basis of your scientific information that leads you to that conclusion.

Dr. **Koop**. All of the studies that have been done in the private sector, in government, the surveillance by the Centers for Disease Control, would indicate that AIDS is not passed by non-sexual, casual contact.

There is no evidence that you can get it by sharing towels, by sleeping in the same bed, by using the same telephone, not even by using the same toothbrush. You do not get it from pets; nor is there any evidence that you can catch it from insects such as mosquitoes.

I think that we have demonstrated as well as one can scientifically that these are factual statements, sir.

The **Chairman**. Your report advocates that voluntary testing for infection be kept strictly confidential. This contrasts with the practice with regard to other venereal diseases where the public health department often traces contacts to decrease the risk of contagion. Why do you feel this practice is inappropriate with AIDS?

Dr. **Koop**. Because the stigma that has been associated with AIDS is real. Many afflicted with the disease or who are infected with the virus are reluctant to be identified with AIDS. And because there is no vaccine and no cure, many feel there is nothing to be gained by revealing their sexual contacts who might also be infected with the virus.

And when a community or State requires reporting of those infected with the AIDS virus to public health authorities in order to trace those sexual or intravenous drug contacts, as is the practice, as you have mentioned, with other sexually-transmitted diseases, those who are infected with the AIDS virus tend to go underground and out of the mainstream of health care and education.

And for this reason, public health practice now in this country is to protect the privacy of the individual infected with the AIDS and to maintain the strictest confidentiality concerning his or her health records.

The **Chairman**. In your report, you state that quarantine has no role in the management of AIDS. Can you explain why this is the case? Are there any situations where quarantine is appropriate?

Dr. **Koop**. First of all, to identify those people who should be quarantined would be a prodigious, probably impossible task, and maybe even cost-prohibitive. You would be dealing with, if you could find them all, as you have already stated, sir, millions of people.

Inasmuch as I have stated that casual, non-sexual contact is not a source of contagion, it does not seem that that kind of quarantine would be worthwhile.

The **Chairman**. Dr. Windom, we are glad to have you here. We have the recommendations. First of all, do you agree with the IOM recommendations on the appropriate level of national AIDS research and public health commitment?

Dr. **Windom**. The IOM's report certainly was well received and we agree with their goals; we hope that they can be achieved. I think that the progress we are making now is certainly going toward that goal, and I think from year to year we will see it increasing.

The **Chairman**. Through the past few days, I have heard the Secretary of Defense and the Secretary of Education. One responds that you cannot solve problems by throwing money at them; the Secretary of Defense believes that probably you can.

Let us put that aside as a debater's point and look at the real allocations of priorities in these areas.

In terms of the dollar figures in the area of research, you have approximately a $91 million increase, up to $413 million, which is not even half of what the recommended figures were in terms of coming to grips in a serious way with this scourge that is giving us 100 percent fatalities.

You have also proposed a very marginal amount for education—you proposed $112 million; again, $1 billion is what has been recommended as figures which could be appropriately, usefully, effectively spent in this area.

We must stress education now, given the certain lag that we have before we can make a use of vaccine available. How do you justify that? Are you going to oppose the efforts that I and others are going to make to try and make sure that you get adequate funding in terms of both the education and the medical research program in the budget?

Dr. **Windom**. Senator, the issue of AIDS is our priority in the Public Health Service and in the Department of Health and Human Services. At this time education is our major effort to really come forth with a means by which we can prevent that disease today.

The funding needs projected for 1991 by the IOM indicate that they agree that we need support and effort from every part of our country. We need the media, which have done an excellent job to date with hour-long or longer television programs, and cooperation in the education effort throughout our society.

Through the Public Health Service as a resource of the knowledge and the best information known today—which will be changing as we go forth—we will be able to provide effective information and education.

I think the progress has been very rapid in that short time, since five-and-a-half years ago this disease was not known. We are stressing and using the funds very adequately, along with support and cooperation from many other segments of our society and government.

The **Chairman**. Well, I am not sure that completely responds to the question, but I——

Dr. **Windom**. In the area of research, we have given top priority to AIDS research throughout the Public Health Service, and we have no plans whatsoever to decrease that emphasis.

As Senator Weicker indicated earlier, the basic biomedical structure that we have in our federal programs and throughout the nation has made it possible for us to advance so rapidly.

So, besides just targeted money for AIDS, there will be many areas of research going on that will have benefits that will spin off to the disease like it has in many other diseases.

The **CHAIRMAN**. Just one or two points. One is I think you can demonstrate quite clearly from an examination of the NIH budget that you are really robbing Peter to pay Paul; that you are taking resources from research in the areas of cancer and a wide variety of other kinds of diseases where there is a high degree of approval of various research programs under the peer review system that ought to be funded and that can really make a very significant and major impact in terms of the quality of health of the American people and siphoning those resources off to the AIDS program.

I will give you an opportunity to respond or you can respond in greater detail, but I think any fair examination of the budget would have to draw that conclusion, and that is wrong; that is wrong.

And I want you to be very clear that we are going to do everything we possibly can to redress that kind of a situation. I would give you an opportunity to comment, if you want, on it.

Dr. **WINDOM**. Senator, each year there has been a continual increase in the awards and the funding of the National Institutes of Health. Also, this next year there will be the highest number of research award grants ever in history. So we do not feel that we are sacrificing other research, but we are trying to bring some stability to that funding level.

The **CHAIRMAN**. Well, as you know, the administration is recommending cuts in NIH of $649 million this year and next year. Senator Weicker makes these points very well as a member of the Appropriations Committee that basically the increases are coming as a result of the actions here in the House and Senate.

I do not want to divert the thrust of these hearings other than to make sure that we put in some perspective, as we begin these hearings and other committees do, about where we are in terms of both the research and the education program.

Dr. Koop, I would just say finally and then I would yield to Senator Weicker, that one of the programs that we see not so frequently or sometimes with children—on those Saturday mornings, you see a whole series of cartoons. There never seems to be any intervention in terms of whether it is AIDS or other public health kinds of questions.

I am sure you are familiar that those cartoons run from God only knows what time, early in the morning until noontime, and it is an ongoing and continuing process. You might just get a look at it and see what opportunity there might be for intervention in those areas.

Having gone through the holiday season with some little grandnieces and nephews and hearing those television programs early in the morning and knowing their rapt attention, there may be an opportunity for early intervention.

Senator Weicker.

Senator **WEICKER**. Thank you very much, Mr. Chairman.

First of all, to the Surgeon General I would like to say that I think this report of yours on AIDS is an outstanding piece of work. Since this is being carried across the country, I wonder if you might tell the average citizen how he or she can obtain a copy of this report.

Dr. Koop. They can write to the Public Health Service and receive this. Let me see if I can find the number. The local Red Cross will supply it. The number you could call in Washington is 202-245-6867, but we have another line which I do not see here. I am sorry. I do not think it is in this.

You can call the hotline for more information on the disease itself and you can get information on how to obtain the report at the hotline number, 1-800-342-AIDS.

Senator Weicker. Well, indeed, if there is any of the Surgeon General's staff here that can supply the mailing address for a request, I wish they would do so because I think that no one book encapsulizes the problem better than this work. While there is no final solution to the problem, the Surgeon General's report certainly highlights those steps that could be taken as a matter of precaution.

I also want to read the conclusion of the Surgeon General's opening letter. I might add this letter, as is indicated in the report—was not written by any staff member; it was written by the Surgeon General.

Dr. Koop says, "At the beginning of the AIDS epidemic, many Americans had little sympathy for people with AIDS. The feeling was that somehow people from certain groups deserved their illness. Let us put those feelings behind us. We are fighting a disease, not people. Those who are already afflicted are sick people and need our care as do all sick patients."

I just want to say both in terms of its science and in terms of its editorializing, this is one good piece of work.

Dr. Windom, I am going to ask some questions that I realize might be a little contentious, but I think they are deserving of some response. I want to point out also to all those attending the hearing that the cooperation which Dr. Windom, as the Assistant Secretary of Health, has given to this Senator, and indeed to the Appropriations Committee, has just been outstanding.

It was largely through his efforts that I was able to achieve additional funding for the clinical trials of AZT on the floor of the Senate last year, and he has been totally responsive to any matter that has been raised before him. I express that as a matter of our personal relationship rather than the budgets, which I plan now to discuss for a minute, knowing full well that those budgets are not devised by you, but probably more devised at OMB than they are at HHS.

The Chairman. Do you feel like you are being battered up before the cooking? Do you think you are being warmed up here a little bit? [Laughter.]

Senator Weicker. No. This is a good man; I mean it. I am not going to get in a fight with him, but I do say that the final determination of our commitment to any problem in this nation is the budget.

It is a very unerring—it is an apolitical document. It is not philosophical. The dollars and cents are there. You can make all the statements that you want, but when it is finally said and done it comes down to are you going to put your dollars out there for the problem.

Senator Kennedy correctly raised the problem that we have here in this year's budget. It is that in the request of the Administration for NIH, number one, they have asked that $334 million in research funds be delayed from fiscal year '87 to fiscal year '88, and then they tack that 334 onto fiscal year '88.

So, really, what you are talking about, since I dare say the delay will not be approved by the Congress, is that there is going to be roughly a $600 million reduction in NIH funding, per the Administration request of '88.

Again, I have to repeat I would rather doubt that the proposed delay and cuts in the NIH budget are going to be approved by the Congress, but it proves to be a real problem insofar as the public is concerned. You cannot go ahead and abandon your basic research.

I am a novice in this thing; I am not a doctor. I never took any science courses; they were far too tough when I was in college. When I was given my choice of a science course at Yale, I took what was known as rocks and stars, which was geology and astronomy, and I stood away from anything else. So I do not pretend to be an expert.

But when I first joined the Committee, for example, progress was being made in conquering the Herpes virus, and you might think that this would be in the infectious diseases area, sexual diseases, et cetera.

Actually, the greatest progress against the virus that was made over at NIH was in the Dental Institute, and I only use that as an example that we do not know where the breakthrough is going to come from and we cannot abandon the funds that go to basic research, as is clearly evidenced by the Administration's budget.

I am going to use their own words, where they say, "Of this total amount, $334 million is derived from a proposal to extend the availability of a portion of 1987 research funds." They then request $5,535,000,000 in new budget authority for FY '88.

Again, further on, "To maintain a balanced program and, at the same time, respond to the public demand for deficit control, the NIH proposes to extend the availability of $334 million in '87 appropriations and defer the spending of this amount until 1988."

And then it says, "In the '87 appropriation"—these are the Administration's words—"the '87 appropriation provided a 17 percent increase in research funding over '86. Such a large increase, especially in research project grants, cannot be sustained without significant displacement of other activities."

Now, this just is not so. Indeed, I have got to say to you that not only do I think there should be additional funding for AIDS, but we should continue the progress that we have made in the basic research across the board accomplished by NIH and through the various grant programs and among the various medical schools and universities of this nation, especially, I might add, with something, to use the common parlance, as flaky as the AIDS virus where you do not know what is going to come next or where it is going to come from.

I know this is tough. Dr. Windom, I do not know if you and I have had an appropriations session yet, but I have gone through this for six years where it is very difficult to elicit from the men of science, which you are, the accurate response when indeed you have had numbers pushed down your throat from a political document rather than a scientific document.

Maybe you read the numbers differently than I do, but if indeed the Administration '88 request does not include a delay of '87 funds, is it true that it will be $600 million less for NIH than in '87?

Dr. WINDOM. Thank you, Senator, for the comments at the beginning and also at the end, and I want you to know that we are very pleased to work with you and cooperate in these efforts.

Now, the question you asked specifically is "Will there be a decrease?" You are correct: Without the carryover provision, the Administration's 1988 request is $600 million less than the 1987 appropriation. This is the reason the carryover proposal is so very important. What we are doing is asking that there be 700 fewer new grants awarded this year. Now, that still leaves 5,600 new grants, new awards, new research projects to be granted.

We are cutting down in the amount in order to take that $334 million and transfer it over to the next year. This does not mean that any of the current research projects that are ongoing will be decreased or stopped.

As you mentioned, it is true that an estimated 65 percent of research performed in one area, something spins off to the other, as you mentioned with Herpes. Those basic research programs are continuing.

So we have to look at the new awarded program request for 5,600 grants, and look at those in priority. Therefore, we are reducing the 6,300, down to 5,600, but still maintaining priority for AIDS because of its impact on the country. We have given priority to that.

So we will have to level off somewhat, but the total number of grants is still high. It is the highest ever.

Senator WEICKER. Fair enough, and I do not dispute exactly what you have said. But, please, everybody understand that what is being said is that within the scientific challenges to this nation, AIDS is a priority.

I come from the point of view that among the priorities of the nation as a whole, science is a priority, and science falls between the cracks as compared to other endeavors of the government where there are substantial increases.

One last question to either you or Dr. Koop, or both. In the Surgeon General's Report on AIDS, you state that in the year 1991—and we are only talking four years from now—an estimated 145,000 patients with AIDS will need health and supportive services at a total cost of between $8 and $16 billion.

Now, mind you, I have just been talking about a $5 billion NIH budget for '88. We are talking, according to the Surgeon General, about $8 to $16 billion in health and supportive services in 1991.

Have any of you got any idea as to how we intend to start to marshal our resources to pay for this tab, and has the Administration been so notified that this problem is coming over the hill?

Dr. **Koop**. I would be glad to defer to Dr. Windom. [Laughter.]

Dr. **Windom**. Yes, sir, it is coming over the hill and from the Hill. We are concerned about this, and that estimation is based upon the information we know today, and that is all we can use to project.

With the mechanisms we have in place and the cooperation of States and local communities in dealing with the disease and management, we need to and we are planning to expend the money and project forward and work toward that goal.

Senator **Weicker**. Well, I thank you very much.

Dr. **Koop**. Senator Weicker, I have the information you requested about how to obtain copies of the Surgeon General's Report.

Senator **Weicker**. Dr. Koop, I wish you would give that information.

Dr. **Koop**. For a free copy of the Surgeon General's Report on AIDS, one could write to AIDS, Post Office Box 14252, Washington, D.C. 20044. By telephone, call either one of these 800 numbers: 800-443-0366 or 800-342-AIDS.

Senator **Weicker**. I just want to repeat on this again, this is the Surgeon General's Report on AIDS. It should be in every home in this nation, and I would ask Dr. Koop once again to give the mailing address and the phone number in order to get a copy of this report.

Dr. **Koop**. The mailing address for a free copy of the Surgeon General's Report on AIDS is AIDS, Post Office Box 14252, Washington, D.C. 20044, and the two telephone numbers, 800-443-0366 or 800-342-AIDS.

Senator **Weicker**. Thank you very much. Thank you, Mr. Chairman.

The **Chairman**. Senator Metzenbaum.

Senator **Metzenbaum**. Dr. Koop, Dr. Windom, I do appreciate the kind of leadership you have provided in this area and your willingness to speak very bluntly and openly about that which is obviously one of the most challenging medical problems this nation has faced in many years.

I am particularly concerned about the problem of AIDS with respect to children. Since 1981, there have been 308 cases of AIDS in children, 187 of whom have died. There are estimates that there are 2,000 children who are inflicted with AIDS but who do not get sick.

Most children got AIDS from their mothers who were drug addicts, and some children are infected through blood transfusions. Some estimate that 100 to 300 babies with AIDS have been abandoned in hospitals by their parents, most of whom are drug addicts.

The fact is that efforts to place these children in foster care or to set up group homes for them have run into community opposition.

In the last session of Congress I succeeded in getting attached to S. 2345 an amendment that would instruct the Secretary to undertake a survey to establish the following: A, the number of children with AIDS nationwide who have been abandoned by their parents and who are living in a hospital environment; B, the number of such children who have been placed in foster care; C, the problems being encountered by social service agencies in placing children in such care; and, D, recommendations for improving the care of pediatric AIDS cases who lack ongoing parental involvement and support.

I cannot think of anything sadder than a little child who has AIDS who is rejected. Nobody wants the child. The child is probably not even aware in some instances that he or she is being rejected, too young to comprehend that.

My question is, even though this amendment was adopted by the Committee, the bill itself never passed, might your office be willing to provide that information for us so that we might see what we could do from a legislative standpoint to help you.

I think if we do not get at the facts with respect to the number of children afflicted with AIDS, we are going to have great difficulty in dealing with the issue.

Dr. KOOP. Senator, I think you remember that my background is pediatric surgery, for 35 years.

Senator METZENBAUM. I know that.

Dr. KOOP. So I share your concern about the children, and although I am not in active practice, I still maintain lines of communication with my pediatric colleagues and the question you have raised is, to them, a very serious one.

One of the problems in a city such as New York is that so many babies born to cocaine-addicted mothers or to a mother who has AIDS are abandoned; I suspect that your estimate is probably low, sir.

I will tell you what is going on in government in reference to trying to come to closure on this issue and answer some of the questions that your amendment addressed.

There will be a meeting next month in Atlanta at the Centers for Disease Control on children's AIDS, and I have been working for several months now pulling together a Surgeon General's Conference on AIDS in Children, to be held at the Children's Hospital of Philadelphia in April.

And I think by the time May rolls around, we will have most of those statistics that you wanted, and I hope will have in place in the private sector better means of coping with the abandonment problem and better means in social service of finding some kind of foster care.

The major problem with foster care, Senator, is that the stigma of AIDS and the misinformation that it is transmitted by nonsexual, casual contact is the barrier to taking care of these youngsters, but I think we can overcome that.

Senator METZENBAUM. And do I understand that as a result of these meetings that probably by about May or later in June, most of the information that we would have obtained through our amendment will be forthcoming?

Dr. KOOP. Yes, sir.

Senator METZENBAUM. Good.

Now, according to a recent press report, an anonymous AIDS testing site in Manhattan has a waiting list that is two months long. What is the situation as you understand it to be with respect to testing, and can people in high-risk groups get tested promptly so that they can have the test without being exposed to the embarrassment and some of the other problems that are obvious, since it does have that kind of stigma attached to it?

Is there any way that you could suggest, a procedure, so that at a minimum, there would be available testing sites where people would be able to protect their identities?

Dr. KOOP. Well, I like to think that that flurry of enthusiasm about voluntary testing, sir, perhaps is in response to the Surgeon General's Report that encourages voluntary testing rather than compulsory testing.

It is, naturally, a problem either for the State or municipal health department. I think the problem is greatest in New York, and I think the backlog you mentioned will be caught up with on the basis of what things I know.

I do not see where the federal government can get into that local jurisdiction in any way, except to give advice and help when asked for it.

Senator METZENBAUM. Can the federal government be a prod? In other words, if you live in Atlanta, the fact that there is a testing site in New York does not help you. If you live in Denver, the fact that there is a testing site in Cleveland does not help you.

It seems to me, that in these conferences and these meetings that you are holding, that there might be an item on your agenda to advocate a prod to establish, wherever possible, these testing sites where people can protect their identity.

Dr. KOOP. All the people who should hear that message are in the audience this morning, sir.

Senator METZENBAUM. Now, Dr. Windom, your testimony outlines many of the activities underway by the Public Health Service relating to AIDS, and I am glad to see that. I think that you are moving very definitely in the right direction.

However, before we congratulate the Administration too heartily on its response to AIDS, we cannot forget that in the initial fiscal year 1986 budget proposal, it called for a reduction in AIDS research and related spending.

Has the Administration been slow to respond, and is it only now starting to respond very actively?

Dr. WINDOM. I think, sir, that the Administration has responded very well and it is progressing each year, realizing more and more the importance and the significance of this disease, and is asking for even more money for fiscal 1988.

Senator METZENBAUM. Dr. Philip Lee, who is the former Assistant Secretary of HEW, recently wrote, "The Department of Health and Human Services has failed to give firm direction to the efforts to understand and control the disease and it has provided no overall strategy or program to guide physicians in how best to care for AIDS patients."

How do you respond to that charge? I want to say that I think the recent report is excellent, but we are talking about an ongoing program and yesterday rather then today. Is there a definite change?

Dr. WINDOM. Yes, sir. We are very actively involved through a number of our agencies. Our Centers for Disease Control publishes weekly a morbidity and mortality report that features AIDS very often, and that is published in the *Journal of the American Medical Association* and other publications.

We have cooperated, also, with physicians in putting on combined conferences throughout the nation for education and information to them. So I feel that we are very actively involved in educating the medical profession.

Senator **Metzenbaum**. I am always concerned about the possibility that there is a lot of research going on, but it fails to have any coordination. I remember many years ago, as a private citizen, I was national co-chairman of the Citizens Committee, Commission, or something, To Conquer Cancer.

I had the feeling that there was not that kind of coordination that was so important and so vital. What kind of federal supervision do we have today to coordinate the various clinical investigations that are underway at this time?

Dr. **Windom**. Senator, we have a very active program among the five agencies of the Public Health Service, a coordinated research task force looking at drugs, vaccines, and also biomedical basic science research, and it is ongoing and increases its efforts all the time.

Senator **Metzenbaum**. How much of the current research is being funded by private sector companies with federal dollars?

Dr. **Windom**. Well, there are grants that the Public Health Service makes to private institutions for research scientists to do research there, and along with those grants from the federal government they also have either State or private funds.

I do not have a figure, Senator, at this moment. We can get that for you if we could figure out the exact numbers. I do not know that, though.

Senator **Metzenbaum**. I would appreciate that figure.

Now, let me ask you, the FDA considers this research, as I understand it, proprietary, and therefore information cannot be made public unless the company agrees. Is that correct?

Dr. **Windom**. Unless the company——

Senator **Metzenbaum**. If federal funds are used and the private drug company conducts its investigation, the FDA, as I understand it, considers the results of that investigation proprietary and the results cannot be made public unless the company agrees. Now, was I misinformed on that?

Dr. **Windom**. Are you referring to the studies that are presented in the information to the FDA for evaluation of the drug?

Senator **Metzenbaum**. Well, I am talking about the research being done by the private sector with federal funds and then the submissions to the FDA for approval to market and the question of where the public dollars fit into that picture and where the public interest fits into that picture.

Dr. **Windom**. Well, public dollars in certain instances are not involved at all because the research is funded strictly by the drug company. If it is in collaboration with studies that are being done at our various health agencies and National Institutes of Health, the federal government is involved in helping direct those research studies, clinical studies, and clinical trials.

Then, in combination, the drug goes to the FDA to see if it is approved for general use and then given to the public. I think there is definitely a correlation with both interests.

Senator **Metzenbaum**. My concern—and the Chairman has pointed out that my time has expired, but my concern is that federal dollars are used. The private company using it, conducting the research, then gets to a point where it wants to go to the FDA, and at what point does this information become available so that not only that company can use it, but other companies as well, and that it becomes a matter of public interest being served?

Dr. **Windom**. As soon as that evaluation has been completed to——

Senator **Metzenbaum**. Pardon?

Dr. **Windom**. As soon as that evaluation has been completed to determine that that drug is safe and effective, and then it goes to the public. I am not aware of any reason that that would be withheld.

Senator **Metzenbaum**. No, but I am talking about the steps before it gets approved by the FDA.

Dr. **Windom**. It has to meet certain criteria of clinical trials to be studied in human beings. Some studies are done by the strictly private sector; others are done in combination because of the work through our National Institutes of Health.

Senator **Metzenbaum**. Well, I have some further questions on this because I am not sure I am satisfied with the response, but we can talk further privately.

Dr. **Windom**. I will try to clarify that later. Thank you.

The **Chairman**. I think if I could just underline what Senator Metzenbaum—I think there is a sense of urgency about this whole proposal which I think we feel, certainly, from being out and talking to our constituents.

We believe that both of you obviously are committed to it, but we are constantly inundated about the slowness of the bureaucracy, the failure of meetings to take place and other kinds of urgency that we hope can be expressed with leadership within the Administration.

I am sure that Senator Metzenbaum has other questions, but that is something that I am constantly asked about.

Dr. **Windom**. Senator, may I answer in response to that, that only in September did we have evidence that there was even a possibility that a drug could be helpful. I have asked Commissioner Young and the FDA to give top priority to evaluation of that drug or any new drug that comes forward that shows promise to go through the process as a priority, and that is being done.

The **Chairman**. Senator Simon.

Senator **Simon**. Thank you, Mr. Chairman, and my apologies for being here just very briefly, but we are voting in another committee and I am going to have to return there.

Just a couple of general observations and then one specific question. One is I am concerned as I look at the NIH budget. I am pleased that we are moving ahead on AIDS research. I hope we do not, as a result of AIDS research, pull back on research on cystic fibrosis, arthritis, cancer, and everything else.

Second, I join my colleague, Senator Metzenbaum, in this tragic situation that affects children, and I am pleased that you are going to Atlanta and moving on this.

Finally, and this is my question, I spoke a few weeks ago at St. Peter's Lutheran Church in Manhattan in New York City, and while I was there for that particular event, they mentioned they have a program to help AIDS victims. They told me how it emerged.

They had one person in their congregation with AIDS and he mentioned there were others with problems, so once a week they started having a meal and counseling for AIDS victims. They now have in a short time 55 AIDS victims showing up at this one church.

There is obviously a desperate need both for the food, I guess for the company, and for the counseling. Are we doing anything to encourage the private sector or public agencies to get involved in that kind of thing?

Dr. KOOP. I think all of us who speak for the Public Health Service around the country, sir, do talk about the effectiveness of the private sector in this regard and encourage it to function.

In preparing my report, I did meet with 26 groups in the country that have interest in AIDS, and they included the National Council of Churches representing so many Protestant denominations; also, the Baptists, the largest Protestant denomination.

We met with the cardinals and the archbishops of the Roman Catholic Church, and also with the Council of Synagogues. And there is no doubt that they may have been slow to awaken to this social responsibility, but I would say that they all expressed a great eagerness to go forward in the kinds of things that you have described at St. Peter's.

Elsewhere, as you may know, in New York, especially under the auspices of that Roman Catholic archdiocese, there has been a tremendous amount of work. St. Claire's Hospital, for example, is a haven for AIDS victims and it has outreach to halfway houses, and so forth.

So I would suspect over the next several years you would see a tremendous increase in the response of the private sector just as you saw at that church.

Dr. WINDOM. Senator, we have four major areas of our country with demonstration projects on managing and handling AIDS patients, and I want to point out particularly that private foundations have also funded a number more of the centers. We are definitely looking toward that area of need to be served.

Senator SIMON. I thank you. Thank you, Mr. Chairman.

The CHAIRMAN. Just a final point that I would like to make. Senator Weicker mentioned what the projected figures would be in 1991 for the care of these victims, as mentioned in the Surgeon General's Report.

The principal way in which many of those victims are going to be cared for is going to be through Medicaid, and yet the Administration is proposing to cut back Medicaid about $20 billion over the next five years.

So I do think if we are going to be fair as a society in coming to grips with this whole kind of issue and work together, it is going to be the research, it is going to be the education, and it is going to be the care, and we have to be realistic. Otherwise, we are really not doing the kind of job that we should.

Senator **Weicker**. Mr. Chairman, just two things. I concur with the Chairman's remarks. Senator Hatch is not here and he has a statement that is going to be placed in the record.

[The prepared statement of Senator Hatch follows:]

Statement of Senator Orrin G. Hatch

Acquired Immune Deficiency Syndrome Hearing

I am pleased that Senator Kennedy is following up on the hearing I chaired last April on Acquired Immune Deficiency Syndrome (AIDS). Our witnesses today will provide more insight and information about what some have called our nation's, and possibly the world's, number one health problem, AIDS.

In my own state of Utah, 49 people have contracted this deadly disease. They are among the 29,435 cases of AIDS reported in this country which have lead to 16,667 deaths. Just last week, 186 Americans died of AIDS. But more are affected. Another 250,000 to 300,000 people have symptoms, called AIDS Related Complex (ARC), from exposure to the AIDS HTLV-III virus. Unfortunately, many of these individuals will eventually develop AIDS. And it doesn't stop there. It is estimated that 1.5-2 million Americans have been exposed to the AIDS virus. At least 30% of those will die within the next five years unless we can find a cure.

For obvious reasons, the Department of Health and Human Services has declared AIDS its number one health problem. It is responding to this epidemic with a three pronged attack -- through research on treatments, through research on a vaccine, and by educating the public about how to prevent the spread of AIDS.

We have heard a great deal recently about new treatments for AIDS. I was pleased to learn that we have finally taken our first small step along this path. One study has indicated that a new drug, AZT, can slow the progression of AIDS. In addition, there are several other studies nearing completion which hopefully will also show encouraging results for other drugs. We have started, but we still have a long way to go.

Over the last 4 years, the federal government spent more than $186 million on AIDS treatment, research, and this year the Reagan Administration has requested $154 million, a 43 percent increase from last year. In addition, private pharmaceutical companies are also investing a great amount of their own capital into finding cures and treatments for AIDS victims.

One area which may require our attention is the Food and Drug Administration's (FDA) approval process. Some critics feel that the traditional cautious approach of the FDA may not be appropriate when facing a life-threatening disease with no known treatment. This is an issue I intend to pursue.

Throughout this discussion, it is important to realize that we are not yet talking about a cure, only slowing the progression of the disease. Most experts feel that a cure is years off. But if a cure can be found, it will be found.

The second prong of our attack has been to work to develop a vaccine. From 1984 to 1988 the federal government will spend more than $110 million to develop a vaccine. Unfortunately, while we have made great progress, there are a number of technical, ethical, and legal problems which stand in the way.

The first step in the development of a vaccine is to learn about the cause of AIDS. We will have invested more than $500 million to learn about AIDS by the end fiscal year 1988. As soon as the virus was identified, several companies started work on vaccines. Fortunately, as you will hear later from Genentech, the field of gene transferring has progressed to the point that it offers the hope of rapidly developing a vaccine.

There are still a number of technical problems. The AIDS virus has the ability to rapidly change. Because of this, more than one vaccine may be necessary.

Once an experimental vaccine is developed, testing it presents a number of problems. Because of the long incubation period of AIDS, any experimental vaccine must be given to large numbers of individuals in order to find out if it is effective. Those individuals would then need to be followed for a number of years. This is both time consuming and expensive.

Giving an experimental vaccine to a large number disease free Americans raises a number of ethical questions. There is always the chance that more people will be injured by the experimental vaccine than are helped. Can we ethically subject a large number of people to that risk?

Even if the technical and ethical obstacles to a vaccine are overcome, there are still legal obstacles. With our current liability situation, many companies are reluctant to subject themselves to the potential liability of producing an AIDS vaccine. More reforms in the areas of medical and product liability may be needed.

The good news is that we can do something about AIDS today. AIDS is a preventable disease and each of us can protect ourselves. We know that AIDS is primarily contracted from IV drug use, sexual contact -- both homosexual and heterosexual -- and now rarely from blood products. And we can now say that there is no risk from casual contact with an AIDS patient.

From 1984 to 1988 the federal government will spend almost $300 million directly on AIDS prevention efforts. Other federal programs will also has an impact on this effort. For example, last year, we authorized $470 million for education and treatment of drug abuse, which should also help prevent AIDS.

While we pursue a vaccine, work on a successful treatment, and continue to educate the public about how to prevent AIDS, we shouldn't forget an important fourth component of our policies -- compassion.

Others of our citizens will die before the fight against AIDS is won. They need our support. They need our compassion. They need the hope of a cure that medical research provides. And they need to have treatment options available. For example, home health care is a viable and compassionate treatment option for many AIDS victims. I will continue to pursue home health care legislation as a reality for chronically ill Americans.

In addition to providing a compassionate alternative to traditional hospital based care, home health care also makes economic sense. In the case of patients with AIDS, health care costs can range from $150,000 to $170,000 from the time of diagnosis to death. Home health care can reduce that cost to around $50,000.

Before I close, I would like to add one personal note. As I mentioned earlier, last year I chaired a hearing on AIDS. One of the witnesses at that hearing was a victim of AIDS, Mr. Nathan Smith, immediate past president of the National Hemophilia Foundation. Several months after that hearing Mr. Smith died from his AIDS. I want to take this opportunity to express my sympathy to his wife and family. He was a courageous example of facing death, while fighting for life.

We are facing a disease today which is taking tremendous toll. We have and will continue to dedicate whatever resources are necessary to stop AIDS. Congress, as always, has a responsibility to see that money is used responsibly. I am confident that we will win our fight against AIDS as fast a humanly possible.

Senator **Weicker**. He has asked that I read the last paragraph of his statement. He says, "Before I close, I would like to add one personal note." This is Senator Hatch, now.

> As I mentioned earlier, last year I held a hearing on AIDS. One of the witnesses at that hearing was a victim of AIDS, Mr. Nathan Smith, immediate past president of the National Hemophilia Foundation.
>
> Several months after that hearing, Mr. Smith died from his AIDS, and I want to take this opportunity to express my sympathy to his wife and family. He was a courageous example of facing death while fighting for life.
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> We are facing a disease today which has taken a tremendous toll. We have and will continue to dedicate whatever resources are necessary to stop AIDS. Congress, as always, has a responsibility to see that money is used responsibly, and I am confident that we will win our fight against AIDS as fast as humanly possible.

Senator Hatch wanted to make certain that that statement was read into the record.

Lastly, a lot of money is being talked about here and I want to make one point, and I get back to the Surgeon General's Report where he said the feeling was that somehow people from certain groups deserved their illness. "Let us put those feelings behind us. We are fighting a disease, not people."

I want to point out, in case there are those who are still sitting in sanctimonious chairs passing judgment on others, that the money that the United States government, the taxpayers, have spent to cure the "normal" sexual diseases over the decades far surpasses the money that we are talking about here.

So let not no one think that for some reason or other this is something special that we are attending to here. When somebody is sick in this nation, as the Surgeon General points out, we take care of them. We try to find the cause of the sickness; we try to cure it.

This is not any time for anybody to go ahead and start pointing fingers at anybody else. This has been our heritage, and it has been our heritage as far as other sexual diseases are concerned and we are doing no more now than we did decades ago. We are all in this together.

The **Chairman**. Thank you very much, Dr. Windom and Dr. Koop. We appreciate very much your presence here.

Our second panel will be the two co-chairs of the blue ribbon National Academy of Sciences Panel on AIDS. They are Dr. David Baltimore, Whitehead Institute at MIT, and Dr. Sheldon Wolff, of Tufts University and the New England Medical Center. Dr. Baltimore chaired the panel on research; Dr. Wolff chaired the panel on education. We appreciate their being with us here today.

We would understand about 20 seconds of restlessness and then we are going to ask for the room to be quiet so we can hear this very important testimony. We have got three panels and, realistically, probably two more hours available to us.

We do not want to inhibit the presentations, but we would indicate to all our witnesses that their statements will be filed in their entirety. We will try and shorten our questions and make them a little more precise, less wordy, but we will try and move along.

Our next two panels are enormously interesting in terms of what is happening in the world and then an update on what is happening with the vaccines, which is going to be, I think, extremely important in rounding out our hearing.

So we will start with Dr. Baltimore. I want to welcome him both as the Chairman of the Committee and also personally. We are glad to have both of you here.

Dr. Baltimore.

STATEMENT OF DAVID BALTIMORE, DIRECTOR, WHITEHEAD INSTITUTE FOR BIOMEDICAL RESEARCH, MASSACHUSETTS INSTITUTE OF TECHNOLOGY, CAMBRIDGE, MA, AND CO-CHAIR, COMMITTEE ON NATIONAL STRATEGY FOR AIDS, NATIONAL ACADEMY OF SCIENCES; AND SHELDON M. WOLFF, M.D., ENDICOTT PROFESSOR AND CHAIRMAN, DEPARTMENT OF MEDICINE, TUFTS UNIVERSITY SCHOOL OF MEDICINE, AND PHYSICIAN-IN-CHIEF, NEW ENGLAND MEDICAL CENTER HOSPITAL, BOSTON, MA, AND CO-CHAIR, COMMITTEE ON A NATIONAL STRATEGY FOR AIDS, NATIONAL ACADEMY OF SCIENCES

Dr. BALTIMORE. My name is David Baltimore and I am Director of the Whitehead Institute for Biomedical Research and Professor of Biology at the Massachusetts Institute of Technology, and a Nobel laureate in medicine.

I co-chaired the study that produced the recent report, "Confronting AIDS," for the Institute of Medicine and the National Academy of Sciences. As part of that task, I also headed a panel on research needs and opportunities.

I should like to emphasize certain points in our report.

The speed and effectiveness with which research on AIDS has been carried out has been phenomenal. The disease was first recognized in 1981, and within two years the first report of a causative agent had appeared.

There followed a veritable explosion of new information about the virus and the diseases it causes. This progress came about as a direct consequence of the many billions of dollars that the United States Congress has appropriated for basic research in biomedical science.

It was a vindication of the longstanding recognition by committees such as this that we must learn all we can about life processes because we never know just what information is going to be relevant to coping with our health needs, a point that both of the Senators have made very eloquently.

The extraordinary success in identifying the agent and in devising a blood test for it has not been followed by great progress on the two fronts we care about most, production of a vaccine and development of an anti-AIDS drug.

Let me describe a bit wherein the problems lie. AIDS is a disease caused by a virus, but the virus has a peculiarity. It does not induce an effective antibody response. The consequence is that the virus continues to grow inexorably in contrast to the usual virus infections which are limited by the body's production of antibodies.

A second consequence of the poor antibody response is that producing a vaccine is going to be very difficult because we will have to trick the virus rather than using our usual tactic of getting the virus to do the work for us.

Drug development is going to be equally hard. No other virus disease has ever been cured by a drug, although some have been held in check. Thus, we have the rare situation of a virus that does not stimulate the body's protective system, where artificial development of protection is probably going to require development of unprecedented strategies, and where drug treatment would be a unique achievement.

Clearly, the AIDS virus poses a uniquely difficult problem to medical science, one to which we cannot expect to have a rapid response. In fact, the speed with which drugs of at least partial effectiveness have been found is amazing and quite gratifying.

The research needed will require the commitment of the entire scientific community inside government, in the academic world, and in private industry. A crucial part of the effort will be work with animals, particularly primates, that provide the only useful models we have for understanding and developing treatments and prevention for the human disease.

To get the involvement of everyone who has something to offer, we need many things. We need to upgrade facilities at universities and research institutes around the country. We need to bring together the private and public sectors. We need to encourage the free and rapid dissemination of research material.

We need to seek out the most innovative members of the scientific community and see that they become involved. We need to increase our efforts in basic immunology and virology to provide the information base for coping with the disease.

We need to expand research on primates and to encourage more trained virologists and immunologists to become interested in primate research. All of this requires money, so we must be prepared for large research expenditures.

On the other side, I think we should avoid tendencies to centralize efforts, to set up czars of research, or to tightly direct programs. Those tendencies stifle rather than encourage creativity.

To optimally deal with the problems posed by the AIDS epidemic, the National Academy of Sciences and Institute of Medicine Committee made a series of recommendations.

First, that we respond now by a massive educational program to limit high-risk activities because we cannot hope to soon enough protect people by a vaccine. Dr. Wolff will comment further on that program.

Second, that we commit ourselves to a long-term research program to find the strategy that will successfully produce a vaccine and to learn the secrets of the virus so that we can most effectively produce drugs. This effort we expect to require $1 billion of research funds by 1990.

Third, we do not try to steal the money for this program from other biomedical research efforts, because we need to be ready to cope with future health emergencies and we have many health problems to deal with other than AIDS.

Fourth, a national advisory panel be established to oversee the anti-AIDS efforts because it requires integration of many sectors, including industry, State and local government, and the federal government.

This should be an ongoing panel that should also serve the necessary function of reporting to the American people periodically on the spread of AIDS and the prospects for control.

Fifth, the President exert personal leadership in the anti-AIDS campaign because a disease that will soon count its victims in the hundreds of thousands is a national catastrophe.

Sixth, the United States play a major role in efforts to understand and curb AIDS internationally because of the enormous magnitude of the problem, especially in Africa; because we have much to learn about how AIDS is spread from studying the problem abroad; and because of the United States' traditional role as leader in world health efforts.

Thank you.

[The prepared statement of Dr. Baltimore follows:]

STATEMENT

by

David Baltimore, Ph.D.
Co-Chairman
IOM/NAS Committee on a National
Strategy for AIDS

before the
Committee on Labor and Human Resources
U.S. Senate

15 January 1987

Statement by David Baltimore, Ph.D., director, Whitehead Institute for Biomedical Research, and professor of biology, Massachusetts Institute of Technology

I was co-chairman of the study that produced the recent report Confronting AIDS for the Institute of Medicine/National Academy of Sciences. As part of that task, I also headed a panel on research needs and opportunities to thwart the AIDS epidemic and control the spread of its causative agent, human immunodeficiency virus (HIV).

The needs of an adequate research program against AIDS are so numerous as to be intimidating. But the imaginativeness of research performed thus far and the swiftness of acquiring knowledge through that research give hope that further success is largely a matter of money and time. Federal money and federal researchers have fostered much of the progress made in understanding AIDS. The funding of future research will continue to be a responsibility of the federal government, but the scientists engaged in it should represent a stronger participation by talented investigators from the universities and from industry.

At this stage in the research effort, time is on the side of the epidemic. That is why a major recommendation of our committee was to employ education and other public health measures that we know how to apply now. We believe that a vaccine against AIDS will not be ready for at least five years and probably longer. Suitable drugs against HIV infection also are a number of years away; promising candidates for drug therapy must yet undergo much testing for efficacy and safety.

A better understanding of the basic biological processes of infection with HIV is required for the development of vaccines and drugs. The same kinds of fundamental research in virology and immunology that have enabled finding the cause of AIDS should lead eventually not only to its control but also to the vanquishing of other diseases.

However, success in these ventures is not assured. The ideal drug against AIDS both must stop the replication of the virus and permit regeneration of the immune system that it crippled. Also, the drug must be easily administered, preferably by mouth; it must be nontoxic over years of use, possibly a lifetime; and it must reach the brain, where infection now is known to have dreadful consequences. No drug has yet been proved to meet these criteria. The situation is similar for vaccines. Development of an immunizing agent against viruses like HIV has never been seriously attempted, much less achieved. Even if the scientific obstacles were surmounted, the legal, ethical, and social difficulties in testing such a vaccine are enormous.

Research needs also are great in the social sciences. Much more must be known about sexual behavior, drug use, and the many other factors that contribute to HIV infection. Social science research can improve the effectiveness of education campaigns aimed at helping people protect themselves against infection.

The methods of epidemiology need to be expanded to enable better surveillance of the populations acquiring HIV infection so that we can determine the future course of the epidemic. In addition, academic laboratories and the ranks of investigators must be expanded. And the supply of laboratory animals, principally non-human primates, needed in research toward drugs and vaccines must be augmented and carefully preserved.

The money that can usefully be spent in this research against AIDS and HIV infection, our committee is convinced, should reach a total of $1 billion a year by the year 1990. These funds must be new appropriations, not money redirected from other health or research programs. AIDS is a new disease, coming on top of all the dread ills we already have to fight.

The diversity of work to be accomplished--both in scientific research and public education--is so great as to elude successful approach by any one entity. Neither the public sector, the private sector, nor any particular agency, organization, or group can be expected by itself to provide solutions to the multifarious problems pose by the disease. All of these approaches and entities must be organizaed in a national effort, integrated and coordinated so that participants are working toward common goals and are aware of each other's activities.

Toward this end, our committee recommended that a new entity--a National Commission on AIDS--be established to meet the need for guidance of the national efforts against HIV infection. The commission would to monitor the course of the epidemic; evaluate research, health care and public health needs; encourage federal, state, philanthropic, industrial, and other sectors to participate; stimulate involvement of academic scientists; and generally track the epidemic and the work to stem it so as to make recommendations for better deployment of the resources demanded by the sweep of the problem.

The commission should achieve its purposes by taking an advisory role and by acting to bring together the disparate groups whose participation is so crucial to halting the AIDS epidemic. The commission should have its own budget for effective operation, but should not dispense funds.

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The **Chairman**. Dr. Wolff.

Dr. **Wolff**. Mr. Chairman, members of the Committee, my name is Sheldon Wolff and I am Chairman of the Department of Medicine——

The **Chairman**. Could you just pull that mike just a little more directly in front of you?

Dr. **Wolff**. Okay.

My name is Sheldon Wolff. I am the Chairman of the Department of Medicine at Tufts University School of Medicine, and Physician-In-Chief of the New England Medical Center.

One of my responsibilities as co-chairman of the IOM/NAS study on AIDS was to chair a panel that examined matters of health care and public health, including public education, entailed in stemming the epidemic of AIDS and the spread of the viral infection that causes it.

The urgency of the situation is only partly portrayed by the official reports of a relentless increase in cases of AIDS. This morning we have heard repeatedly about the large numbers of patients both infected and suffering with AIDS in this country today.

Most persons with AIDS can be expected to die within two years; hardly any survive past the third year. The larger dimension of the damage is that these victims are only a small proportion of the people already infected with this virus.

A very much larger population, however, is not infected with the AIDS virus, even though some of them are in high-risk groups for infection. These are the people who must be reached by a massive and continuing public education campaign to teach them how to avoid infection.

Such a campaign was a central recommendation of our study. We found that education offered the only hope of slowing the spread of the virus over the years that we expect it will take to devise an effective AIDS vaccine or therapeutic agent.

Education, as we mean it, includes inducing, persuading, and otherwise motivating people to avoid transmission of the virus. The message must be as direct as required to impress the target audiences of the peril of the infection and how to avoid it.

Target groups include homosexual men, intravenous drug users, sexually-active heterosexuals, and adolescents. Whatever vernaculars it takes to reach them are the languages that educators must employ.

Our committee expressed disappointment in past federal education efforts against AIDS. In fact, we described it as woefully inadequate. However, we were pleased to see the report of the U.S. Surgeon General on AIDS which was released shortly before our report, and believe that it is a step in the right direction.

Along with the education campaign, we recommended other public health measures, including an expanded program of testing for infection that is both voluntary and confidential, stronger efforts in treatment and prevention of intravenous drug use, and experiments in furnishing sterile needles and syringes to intravenous drug users.

All told, the education and public health measures that we recommended, can be expected to cost approximately $1 billion a year by the end of 1990. However, those expenditures are to be shared among federal, State, local and private sources.

An idea of the expenses that can mount up to $1 billion a year is given by only a few examples. Testing for infection, including counseling, is estimated to cost approximately $40 per person. Twenty million people in this country need to be tested, as a conservative estimate.

The five States leading in spending for AIDS prevention have gone through $117 million in two years, but have had to tap other State health programs to raise the money. Advertising will be needed to push the message of prevention. Conceivably, we may have to spend as much as it costs to launch a laundry detergent, which is approximately 50 to $60 million.

These figures pale, however, in comparison with the cost of caring for AIDS patients and persons afflicted with other expressions of the virus. The annual cost of care for AIDS patients at present is estimated to be between 20 and $60,000, while the lifetime cost per AIDS case is seen to range from 50 to $150,000 per patient.

Thus, one could estimate, as was mentioned earlier this morning, that it will cost between 8 to $16 billion in 1991 just to care for patients with AIDS. Against such figures, the investment value of preventing each new AIDS case is a huge bargain.

The high cost of care for AIDS patients already has grievously burdened hospitals and other facilities in some urban centers with a large number of cases. Similar problems can be expected in the next few years to engulf facilities not familiar with AIDS. They will need the advice of those who have learned which techniques of care work best.

Our committee found the most appropriate care emphasized community-based services that keep hospitalization to a minimum. We already see our recommendations reflected in the recent Massachusetts decision to fund home care for AIDS, which may be the first such action in the nation.

International problems with AIDS and infection by its virus have yet to provoke an adequate response from the United States. Particularly in developing nations, and especially in the nations of Central Africa, the rate of infection with the virus is reportedly as great as ten percent.

Such an involvement with such a dread disease imperils not only further development of these struggling countries, but also the very survival of their most deprived sub-populations.

These countries have so few health resources that they cannot begin to cope with AIDS unless the United States joins in research to benefit them and, consequently, us. We also should support the newly-expanded AIDS program of the World Health Organization. It was our recommendation that by 1990, our total commitment to international efforts should total at least $50 million a year on a continuing basis.

Thank you.

[The prepared statement of Dr. Wolff follows:]

STATEMENT

by

Sheldon M. Wolff, M.D.
Co-Chairman
IOM/NAS Committee on a National
Strategy for AIDS

before the
Committee on Labor and Human Resources
U.S. Senate

15 January 1987

Statement by Sheldon M. Wolff, M.D., chairman, Department of Medicine, Tufts University School of Medicine, and Physician-in-Chief, New England Medical Center Hospital

I served as co-chairman of the Institute of Medicine/National Academy of Sciences study that issued the recent report, Confronting AIDS. My particular purview in that study was a panel that examined matters of health care and public health, including public education, entailed in stemming the epidemic of AIDS and the spread of the virus infection that causes it.

The urgency of the situation is only partly portrayed by official reports of a relentless increase in cases of AIDS--currently about 35 new cases a day in the United States. Most of those persons can be expected to die within two years; hardly any survive past the third year. The larger dimension of the damage is that these victims are only a small proportion of the people already infected with the virus. In five years, 10 times as many AIDS cases will have been reported.

A tremendously bigger population, however, is not infected with the virus, even though some of them are in high-risk groups for infection. These are the people who must be reached by a massive and continuing public education campaign to teach them how to avoid infection.

Such a campaign was a central recommendation by our study committee. We found that education offered the only hope of slowing the spread of the virus over the years that we expect it will take to devise an AIDS vaccine or therapeutic drug.

Education, as we mean it, includes inducing, persuading, and otherwise motivating people to avoid transmission of the virus. The message must be as direct as required to impress the target audiences of the peril of infection and how to avoid it. Target groups include homosexual men, intravenous drug users, sexually active heterosexuals, and adolescents. Whatever vernaculars it takes to reach them are the languages that the educators must employ.

Along with the education campaign we recommended other public health measures, including an expanded program of testing for infection that is both voluntary and confidential, stronger efforts in treatment and prevention of intravenous drug use, and experiments in furnishing sterile needles and syringes to drug users.

All told, the education and public health measures we recommended can be expected to cost $1 billion a year by the end of 1990. However, those expenditures are to be shared among federal, state, local, and private sources. An idea of the expenses that can mount up to $1 billion a year is given by a few examples. Testing for infection, including counseling, is estimated to cost $40 per person; 20 million people to be tested is a conservative estimate. The five states leading in spending for AIDS prevention have gone through $117 million in two years, but have had to tap other state health programs to raise the money. Advertising will be needed to push the message of prevention, conceivably as much as has been spent to launch a new laundry detergent: $50 to $60 million.

These figures pale in comparison with the costs of caring for AIDS patients and persons afflicted with other expressions of the virus infection. The yearly cost of care for AIDS patients is estimated at $20,000 to $60,000, while the lifetime cost per AIDS case is seen to range from $50,000 to $150,000. Against figures such as these, the investment value of preventing each new AIDS case is a huge bargain.

Our committee expressed disappointment in past federal education efforts against AIDS. However, we were pleased to see the report of the U.S. Surgeon General on AIDS, released shortly before our report, and believe that is a step in the right direction.

The high cost of care for AIDS patients already has grievously burdened hospitals and other facilities in some urban centers with a large number of cases. Similar problems can be expected in the next few years to engulf facilities not now familiar with AIDS. They will need the advice of those who have learned which techniques of care work best. Our committee found the most appropriate care emphasized community-based services that keep hospitalization to a minimum. We already see our recommendations reflected in the Massachusetts decision to fund home care for AIDS, which may be the first such action in the nation.

International problems with AIDS and infection by its virus have yet to provoke an adequate response from the United States. Particularly in the developing nations, and more especially in the nations of Central Africa, the rate of infection with the virus is anecdotally reported as great as 10 percent. More than six percent of employees at one hospital there were found recently to test positive for contact with the virus. Such an involvement with such a dread disease imperils not only further development of the struggling country, but also the very survival of its most deprived subpopulations.

These countries have so few health resources that they cannot begin to cope with AIDS unless the United States joins in research to benefit them and, consequently, us. We also should pitch in with the newly expanded AIDS program of the World Health Organization. By 1990, our total commitment to international efforts should total $50 million per year on a continuing basis.

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The **Chairman**. Thank you very much, Dr. Wolff, for your presentation.

If we start with Dr. Baltimore, the IOM recommended $1 billion a year for expenditures on research on AIDS by 1990. Why do we need to spend so much money?

Dr. **Baltimore**. We need to spend so much money because it is such a complicated problem. It takes in so many different disciplines and, as I said, it involves inventing new methods of vaccine production, new methods of drug development that have not existed before, have not had to exist before.

These are expensive matters partly because we do not know where we are going, and so we have to take every avenue of approach that might conceivably be helpful. Also, the need for primates makes it a very expensive business because they have to be cared for carefully and humanely, but they are very necessary in trying to develop models so that we can understand the transmission of the virus.

We do not actually understand the transmission of the virus extremely well in human beings at all. We know who gives it to whom, but we do not really know how. Those kinds of things could be learned, I think, only by studying primate models.

So there are huge expenditures necessary. There are very expensive kinds of research necessary, and we have to bring whole groups of people into the problem who have not been involved previously, including the academic scientific community.

The **Chairman**. The Administration recommends $413 million for research in '88. What is your medical and scientific evaluation of whether that is sufficient?

Dr. **Baltimore**. To my mind, that is not sufficient. We were very pleased to see that the Administration had recommended an increase in the AIDS budget, but our own projections—and they are not precise to the dollar—were that it would take $1 billion by the 1990 budget.

And projecting that back to this budget, I would think that this budget should provide something over $500 million for AIDS research.

The **Chairman**. Do you know where you would put the additional money?

Dr. **Baltimore**. I would have to do a detailed analysis of where the needs are.

The **Chairman**. But you are satisfied that there are——

Dr. **Baltimore**. I think there are many opportunities where that money can be used very effectively.

The **Chairman**. It has been proposed that we have a national commission on AIDS. What would it do?

Dr. **Baltimore**. I think it would help the American public to make a continuing assessment of the developments in this area. It would help to coordinate activities between groups that have not historically been involved with each other, particularly the research efforts in private industry and the research efforts in the public sector.

It would help to assess the international situation and see its relevance to the United States. We do not see it as a commission that is directing research or that becomes the conduit for research funds, but rather a kind of overarching commission that will look at the problem broadly and help people cope with what is an increasing burden on the society in so many different directions. As Dr. Wolff had said, this includes health facilities as well as research.

The **Chairman**. Let me ask Dr. Wolff, one of the knottiest problems that we face, it seems to me, is how to conduct a comprehensive education program without offending the sensibilities of many people on these delicate subjects.

What is your feeling about how we ought to proceed?

Dr. **Wolff**. As you might imagine, we have discussed this subject in great length and we share your concern about offending people's sensibilities. On the other hand, we feel that to allow this disease to continue unchecked is much more offensive.

We believe that there are means for educating people in a tasteful way, but nevertheless getting the message across. We feel very strongly that one has to be explicit. In other words to "say it like it is" if we are to get through to the groups that we are interested in reaching.

Certainly, there are some other very sensitive issues that seem to be handled in very open ways in our media without offending a lot of people's sensibilities.

The **Chairman**. No problems in killings and shootings and violence on the television.

Dr. **Wolff**. Right, correct.

The **Chairman**. And yet sometimes there is hesitancy in matters which can make the difference between life and death.

What leads you to believe or what evidence is there that these education campaigns, these efforts to change behavioral patterns, can really be effective?

Dr. **Wolff**. Well, there is some correlative evidence. When the gay community——

The **Chairman**. There is what kind of evidence?

Dr. **Wolff**. There is supporting evidence.

The **Chairman**. Fine.

Dr. **Wolff**. When the gay community began very intensive local educational activities in places like San Francisco there was much wider use of condoms and associated sexually-transmitted diseases such as anal gonorrhea dropped by 90 percent within a year.

Since we know the use of condoms will stop the passage of virus into the recipient, we believe that the same thing would happen.

The **Chairman**. Do you want to comment on the Administration's budget figures again in order that we have some kind of guidance as we go through this process in terms of staking out priorities?

Dr. **Wolff**. Yes.

The **Chairman**. It is about $121 million.

Dr. **Wolff**. Yes.

The **Chairman**. We recognize, as Dr. Baltimore said, we are not just talking about federal; we are talking about States, local communities, groups, business, church groups, and others.

But given the amount of your own consideration, the consideration of the commission on this issue of education, are there enough resources there, with $120 million, to do the kind of job that should be done?

Dr. **Wolff**. No, as you know, we asked that $1 billion be made available by 1990 for public health measures and public education. This money was not just for advertising or just for public education. It was for testing, it was for counseling, it was for trying to improve in some way the handling of drug abuse; not the interdiction of drug abuse, but rather the treatment of drug abusers.

We heard in some of our hearings in New York, for example, that methadone clinics were over-subscribed; drug abusers could not get into them. It cost about $3,000 a year to maintain a patient on methadone. It costs up to $150,000 to treat a case of AIDS. We think that the trade-off is considerable.

The **Chairman**. I would ask you both, on the recommendation of the Administration in terms of the budget, we have this reduction in NIH. As research scientists who are strongly committed on AIDS, is this a troublesome factor? Are you concerned not only about the priority that AIDS has, but are you concerned about the withdrawal of funding for these other areas of research as well, Dr. Baltimore?

Dr. **Baltimore**. Absolutely. The opportunity that we have today to understand the basic cellular processes that lead to diseases like cancer, heart disease and others, those opportunities are without precedent in history.

We could be doing a tremendous amount more work today than we are, and the only limitation is funds. The scientific community consists of people very well trained and very dedicated to research activities and, really, the limitation on how much they can accomplish, how much more they can learn about cancer, how much more they can learn about AIDS, how much more they can learn about the fundamental virology and immunology that is behind so many diseases is the limitation of funds.

To see the Administration recommending that money be taken from this year's budget and that next year's budget be even less is, to me, shocking and seems to me to be a total misreading of what the priorities of this country ought to be.

The **Chairman**. Dr. Wolff, do you want to make a comment?

Dr. **Wolff**. Yes, Senator Kennedy. I would like to emphasize and support what Dr. Baltimore just said and what you and Senator Weicker have said earilier. I would like to add that I think it is incredibly short-sighted.

Let us suppose that we were lucky and in five or ten years we had a treatment for AIDS and a vaccine for it. There would have been precious time lost in dealing with other very important diseases.

Most importantly, I would like to take exception to one of the things that the Assistant Secretary said this morning. I agreed with many of the things he said. However, when he said that a cut to 5,600 grants this year would not affect new grants, I think that that is patently wrong.

You cannot cut 700 grants out of the NIH's budget and not expect very disastrous consequences in the scientific community, and I think those consequences will be far-reaching.

The **Chairman**. I am sure that that is a pretty good cue for Senator Weicker to come in. I would just ask you whether both of you believe—you are scientists, you are researchers, leaders in this area of research and education.

Would it make a difference if the President became involved in this in terms of providing leadership on it?

Dr. **Wolff**. Yes. I would urge him in the strongest terms to take a strong leadership role. I think it would be most important.

The **Chairman**. Senator Weicker.

Senator **Weicker**. Thank you very much, Mr. Chairman, and I very much appreciate the testimony of the two witnesses, but I sort of come to expect that of the National Academy of Sciences both in terms of your testimony and your report.

And, indeed, when a problem arose at the Centers for Disease Control that might have been misunderstood by the public, I turned to my good friend, Sam Thier, and asked that the Institutes of Medicine investigate the problem so there could not be any political connotations to it, and the Institutes of Medicine just did an outstanding job.

To show what foresight is all about—and you indicated that various members of the Administration might have been somewhat short-sighted—I point to this book that was put out. This is the report that you gentlemen put out, and there is a sentence in here I think I should read because it came forth before the '88 budget was released.

> These funds must be newly appropriated, not money taken from other research, because the nation's general health efforts as well as those directed against HIV need continuing progress in basic biomedical science on a broad front.

So these fellows are not being sort of attuned to the politics of the times; they made this very clear in their report before the budget came out.

Now, I would like to, if I might, just get to the two items, the $1 billion for research that you recommend and the $1 billion for education. If we continue at the requested level for '88 by the Administration, we would be roughly in that ballpark of the $1 billion.

In other words, there is $344 million requested for fiscal year '88, and to project that out, in other words, for a three-year period we would be within that $1 billion ballpark.

I am now talking about research, not education; I am going to get to that in a minute because we have very little there. But in other words, that figure of $1 billion, do you consider that to be a sound figure as to what we should be seeking in the period of time '88 to '90?

Dr. **Baltimore**. We were actually talking about that as a yearly figure, not as an aggregate.

Senator **Weicker**. That is a yearly figure?

Dr. **Baltimore**. Yes, that is right.

Senator **Weicker**. Okay, all right, so we are actually talking about $3 billion by the year 1990, then?

Dr. **Baltimore**. Well, escalating up to that. No research program can jump from $200 to $1 billion in a year without gross inefficiencies. So we saw the country developing its programs in a measured way, roughly doubling its efforts yearly, and that would bring us to about $1 billion.

Senator Weicker. Now, the reason why I am especially concerned about this figure is—I will tell a little secret out of school here and I hope I do not get anybody in trouble, but for the past several years, the past two years at least, I have met unofficially with various and sundry persons both within NIH and those working with NIH to ask the question as to what was actually needed in terms of research dollars by the NIH.

Whatever that figure is, I have always come up with it in the appropriations process, regardless of what the Administration budget was. We all know—it is no great secret around here—there has been no HHS budget, in other words, devised by the doctors and the scientists at NIH.

It is done at OMB, and I will tell you, when I asked OMB if they had a doctor or a scientist over there that helped divise the numbers, they said absolutely not. They do not have anybody over there that knows anything in the area of your expertise, but they are the ones that devise the budget.

What I am worried about, in other words, is I think it is terribly important that we be able to responsibly digest whatever monies Senator Kennedy, myself and others are going to fight for here in terms of AIDS research.

If, indeed, we have been falling short—and I am saying within the last two years, not before that, because I think before that we have a huge shortfall—I would certainly hope that the National Academy would work with us, in addition to those that I have had to work with surreptitiously, in getting straight information.

What I am saying is I do not want us to fall into the Pentagon syndrome of just throwing money out there and seeing money wasted, because then the credibility of the scientific community will be in danger.

Dr. Baltimore. Senator, I could not agree with you more. I think that we were making a projection of what we thought would be needed, but I think the yearly appropriation process has to look at what it is we can really do and what monies can really be used.

It is my impression that more money could be used in the 1988 budget than is there. How that should project in '89 and '90 and beyond that, we made a guess at, but I think we have to take a look at that guess each year and see where we are and see what is coming along.

If, for instance, there are major breakthroughs on either the vaccine or drug front, then the picture changes enormously. On the other hand, if many of the things that look promising today turn out not to be as promising as we hope, we may say, well, we have got to redouble our efforts.

It will also depend very much on how effective we are with the educational program. If we could truly prevent the spread of this virus within the population by educational activities, then we might see a different level of necessity in the development of vaccines and drugs.

On the other hand, I think most of us suspect that as hard as we try at education and public health measures, they are likely to be only partially effective, leaving a big part that will have to be dealt with by the traditional methods of dealing with infectious disease.

Senator **Weicker**. Well, now I will get to Dr. Wolff's side of this. There is no $1 billion or anywhere near it for education. There is almost nothing.

Staff indicates to me that $120 million is currently projected for education. That is far short of the $1 billion that you recommend. Would you like to address that?

Dr. **Wolff**. Yes. Again, I would like to emphasize that the $1 billion is not just for public education, but it is also for other public health measures to make sure that there are adequate facilities available for testing and for counseling, to make sure that there are adequate detoxification facilities available for people.

We do believe, however, that a massive public education effort, which would include not just sex education in the school, not just TV advertisement, but to reach the groups at risk and the population as a whole, will cost considerably more than is presently being spent and, in toto, by 1990 should reach $1 billion.

Senator **Weicker**. All right.

Dr. **Wolff**. If I may add one thing, Senator, in addition to what my colleague has said.

Senator **Weicker**. Please, please.

Dr. **Wolff**. All morning, we have talked about research. One of the things that is going to cost a great deal of money and we are going to have to come to grips with in this country—in the last number of years, we have done nothing about our physical plants and our instrumentation, and our laboratories in this country in many places are too old; they are antiquated, they are inefficient. Much of our instrumentation, in fact, is outdated.

And in addition, order to do research in retroviruses, you need certain kinds of specialized facilities. In order to stay competitive scientifically with the rest of the world, I would hope that your Committee, Mr. Chairman, would begin to deal with the fact that through the years we have neglected physical facilities; we have neglected instrumentation.

Senator **Weicker**. Well, I could not agree with you more. I mean, I cannot tell you how delighted I was to have Senator Kennedy provide the opportunity for these hearings and then to have the expertise and the eloquence of those of you that are testifying come to the attention of the American public, because you are entirely right.

Whether it is research, whether it is the infrastructure or the facilities, et cetera, this nation has absolutely neglected this to the point where we have got a tough row to hoe.

I can only, number one, assure that in the appropriations process, which I have some say over, I will ask all of you to testify again. But is it not amazing how in this nation we say to each other as individuals that if you do not have your health, you do not have anything?

That is said a million times a day across this country from individual to individual, but do we say it nationally as a matter of priority? No, no. We do not have anything as a nation if we do not have our health, but we are not willing to go ahead and make that true insofar as our spending priorities.

Dr. **Baltimore**. There is perhaps one other piece to this puzzle that might be worth putting on the table, and that is that even the funds that are today appropriated, if you look back at where those funds came from, a lot of them were taken from other programs.

Senator **Weicker**. Yes.

Dr. **Baltimore**. So the business of taking from other research programs to develop the AIDS budget has been going on for a while, and one of the aspects of the $1 billion that we recommended was to return those funds, partly because of the problems of infrastructure and partly just the problems of the progress in the various areas of research in the country.

Senator **Weicker**. Well, I concur with you. Granted, our job on Appropriations has been incomplete, but we have tried mighty hard to stem what have been just large, massive onslaughts, if you will, by the Administration into this area.

Indeed, it is one of the major reasons why, insofar as my own party is concerned, I am the turd in the punchbowl. I think we have done as well as can be expected and now, hopefully, we will be able to move on to a more positive element.

On the matter of education that Dr. Wolff refers to, the importance of that—you can disagree if you will, but I think you would probably concur that we can spend, for example, in the area of drugs—everybody wants to have a war on drugs and they want the U.S. militia and the National Guard called out, and the Army; get more helicopters, use the Air Force, bolster up immigration. We go on and on and on.

There is only one way to stop the abuse of drugs. You will never stop that stuff coming into this country. What you have got to stop is the use, and if you would educate our children from two years of age on that it will kill you, that will stop the problem. Nothing else will.

The same holds true as to what you are recommending here insofar as any effective response to AIDS while the research goes on.

I thank you.

The **Chairman**. I wish Senator Weicker would be a little clearer about his views. [Laughter.]

It is always a pleasure. Thank you very much to the panel.

Dr. **Baltimore**. Thank you.

Dr. **Wolff**. Thank you.

The **Chairman**. For our next panel, I would like to welcome Dr. Jonathan Mann, the AIDS Coordinator for the World Health Organization. Two months ago, WHO announced an international plan for facing the AIDS crisis, and we look forward to hearing about the worldwide scope of this deadly plague.

I would like to welcome Dr. St. John of the Pan American Health Organization, who is coordinating AIDS activities in this hemisphere. We have had the good opportunity to work closely with Dr. Mahler and the World Health Organization. We hope that you will give him my best personal regards. We admire the leadership that he has provided in the World Health Organization and are very mindful of the very important service that they provide in many different areas of health policy.

We are delighted to have Dr. St. John here as well. We have had a chance to work closely with PANAHO and other organizations, particularly in the work of immunization of children in Central America and other health areas which has been enormously impressive. I think it has been sort of the one small silver thread in an otherwise gloomy situation, certainly, in El Salvador and other Central American countries, the work that has been done by PANAHO.

We have got a major new challenge. We will look forward to hearing from each of you. We will start with Dr. Mann.

STATEMENT OF JONATHAN M. MANN, M.D. DIRECTOR, SPECIAL PROGRAM ON AIDS, WORLD HEALTH ORGANIZATION, ACCOMPANIED BY RONALD ST. JOHN, M.D.

Dr. MANN. Thank you very much, Mr. CHAIRMAN. AIDS is a global health problem for both the developed and the developing world.

The CHAIRMAN. We will be quiet now, if we could, please. We have all been very courteous. This has been a very instructive and important hearing and we want to make sure that our witnesses are given all the courtesies which they are entitled to.

Dr. Mann.

Dr. MANN. Thank you very much.

AIDS is a global health problem for both the developing and the developed world. The numbers of reported cases and the numbers of countries reporting cases have both increased dramatically.

In December 1982, 711 AIDS cases were reported from only 16 countries. As of early this week, nearly 39,000 cases of AIDS have now been reported from 85 countries representing all continents, for a more than 50-fold increase in the number of reported cases in the last four years.

In the Americas, 33 countries have reported AIDS. In Europe, there have been approximately 4,000 AIDS cases reported thus far, and we estimate there are between a half a million to one million infected persons, such that by the end of 1988, 25 to 30,000 cases of AIDS are expected in Europe.

In Asia, the AIDS virus is starting to threaten that continent, and although there have only been fewer than 100 cases of AIDS reported from ten countries in Asia, the virus has penetrated the high-risk groups, cases have occurred, and the future of the continent may be at stake in terms of the question of whether the virus penetrates the large populations of Asia in the future.

Africa is clearly the most affected part of the world. The World Health Organization estimates that there are between two and five million Africans infected with the AIDS virus now, and we know that in parts of central, eastern and southern Africa, between 4 and 15 percent of healthy adults are currently infected with the AIDS virus.

By 1991, we expect that there will be up to 1.5 million new cases of AIDS occurring in Africa, resulting exclusively from people already infected with the virus.

Worldwide, the World Health Organization estimates that there have been over 100,000 cases of AIDS since the beginning of the epidemic and that five to ten million persons may be infected throughout the world.

By 1991, we expect that there may be 50 to 100 million infected persons, and this all depends on what happens in Asia and South America. If the virus penetrates those large populations, those estimates will be conservative.

Worldwide, the broad impact of the AIDS virus infection goes beyond the health statistics to realities and to fears. All over the world, there have been personal and family tragedies as a result of fear and ignorance about this virus.

The loss to society has occurred in at least two ways; first, through the selective loss of 20- to 40-year-olds—in other words, fathers and mothers—and, secondly, through the stigmatization of different groups in different societies.

While in one society homosexual and bisexual men may be stigmatized, in other parts of the world hemophiliacs, female prostitutes, Westerners, or Africans are stigmatized.

At the national level, AIDS poses a threat to economic and social development and stability, particularly in those parts of the world where the urban elites are particularly severely affected.

In addition, AIDS has provoked reflex reactions at the international level, reactions to restrict international travel or trade, reactions to blame others—often on the basis of political expediency—to blame others for the problem.

Finally, threat to children is critical because AIDS poses a direct threat to the success of the child survival initiatives which have so painstakingly been put into place in the developing world.

AIDS is a dual threat to children in the developing world, first because when the mother is infected the child may be infected. There are parts of central and eastern Africa where ten percent of pregnant are infected with the AIDS virus, such that five percent, or one in twenty, of all children born in those areas are born infected with the virus.

But, in addition, children are particularly susceptible to diseases such as malaria which result in a need for injections, which may be given with needles and syringes that are not sterile, and a need for blood transfusion in areas of the world where blood is not screened and where one out of every ten units of blood may contain the AIDS virus.

If we look overall, therefore, at the stresses to society created by the 100,000 cases of AIDS that have occurred thus far, then we have to project what more than a million new cases of AIDS occurring in the next five years will mean globally.

Global AIDS prevention and control requires, first, a recognition of the problem. We could really call 1986 the year of global AIDS awareness, the year when countries and people began to realize that this is not a problem restricted to one group; that this is truly a global problem.

On November 20th of last year, the Director General of the World Health Organization announced that in the same spirit with which WHO undertook smallpox eradication in the past that WHO was undertaking now the more urgent, more complex and more difficult task of global AIDS prevention and control.

This will require the development of strong national AIDS prevention and control programs in every country throughout the world and international leadership, coordination and cooperation.

WHO started its AIDS program in 1986 and we received a very vital initial moral and financial support from the U.S. Agency for International Development which allowed us to start as quickly as we did.

We have developed a 1987 action plan; it is in the discussion phase with the donor agencies throughout the world.

In summary, AIDS is truly a global health problem. The consequences of AIDS virus infection at the personal, family and social level are profound. AIDS threatens the limited health gains that have been achieved, particularly in the area of child survival, throughout the world and it threatens economic and social development.

The epidemic of this virus is of extraordinary scope and unprecedented urgency, and requires a response of unprecedented energy, creativity and resource. We are, Mr. Chairman, truly at an historic moment, at the beginning, really, of a worldwide epidemic whose dimensions and scope we are only beginning to truly understand.

It is clear that actions that we take now have greater potential to affect the ultimate shape of that epidemic than actions taken in the future.

Thank you, sir.

[The prepared statement of Dr. Mann follows:]

The World Health Organization's Perspective on AIDS:

Global Dimensions and Prospects for Prevention and Control

Jonathan M. Mann, M.D., M.P.H.
Director, Special Programme on AIDS
World Health Organization
Geneva

January 15, 1987

I am pleased to appear here today to speak on behalf of Dr. Halfdan Mahler, Director General of the World Health Organization, who was invited by the Senate Labor and Human Resources Committee to provide testimony to this Committee. The Executive Board of WHO is underway and Dr. Mahler requested that I represent him and the Organization as Director of WHO's Special Programme on AIDS.

When the Acquired Immunodeficiency Syndrome (AIDS) was first recognized in 1981, the disease appeared limited to a single nation and to a single group characterized by its sexual orientation. Today, as a result of extensive national and international collaborative research, the worldwide epidemic of human immunodeficiency virus (HIV) and related retroviruses* is recognized to be an international health problem of extraordinary scope and unprecedented urgency.

I. Global Dimensions

Numbers of reported cases of AIDS and countries reporting AIDS have increased dramatically. As of December 1982, 711 AIDS cases were reported to the World Health Organization (WHO) from only 16 countries. However, by 5 January 1987, 37,872 AIDS cases were reported to WHO from 85 countries representing all continents.

AIDS Cases Reported to WHO: 5 January 1987

Continent	No. of Cases	No. of Countries
Africa	2323	17
Americas	31230	33
Asia	86	10
Europe	3847	23
Oceania	386	2
TOTAL	37872	85

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* The name "human immunodeficiency virus" has replaced the earlier names for the "AIDS virus", including "Human T-lymphotropic virus type III" and "Lymphadenopathy-associated virus". The related retroviruses include LAV-2, HTLV-4 and other recently recognized retroviruses infecting humans and which are considered related to HIV, with or without evidence of immunosuppresion or clinical disease. In this document, "HIV" stands for all of these viruses.

An additional 40 countries (Africa - 17; Americas - 11; Asia - 8; Europe - 4) have informed WHO that they thusfar have no AIDS cases to report. Reticence in reporting of cases from some areas, combined with under-recognition of AIDS and under-reporting to national health authorities, has meant that the number of reported AIDS cases represents only a fraction of the total cases to date; these are estimated to be in excess of 100,000. Therefore, WHO considers the number of countries reporting AIDS cases to be more indicative of the geographical extent and more relevant to an assessment of the scope of the HIV pandemic than the number of officially reported cases. In addition, due to the long incubation period (up to six years or longer) from HIV infection to the development of clinical disease, the number of AIDS cases provides, at best, an inaccurate and at worst, a misleadingly optimistic view of the real extent and intensity of HIV infection. Worldwide, WHO estimates that between 5 and 10 million persons or more are currently infected with HIV. Finally, recent recognition of additional pathogenic human retroviruses in West Africa and apparent identification of an AIDS-like retrovirus in South America suggest the possibility that HIV may be the first of a series of retroviruses recognized to be capable of infecting humans and producing immunosuppression.

A. The Americas:

In the Americas, 91 percent of cases (28,523 of 31,230) have been reported from the United States where the epidemiological characteristics may be considered typical of "Western" AIDS. The United States Public Health Service has estimated that approximately 1.5 million US residents are HIV-infected and that 270,000 AIDS cases will likely have occurred by 1991. Several other countries contribute substantially to the AIDS case total for the Americas, including: Canada (755), Brazil (754), Haiti (501), Mexico (161), and Trinidad and Tobago (108). With the exception of Haiti and possibly other Caribbean areas, the epidemiological pattern appears "Western", primarily involving homosexual and bisexual men and/or intravenous drug users. The epidemiological pattern in Haiti appears intermediate between the "Western" and the "African" pattern described below. Finally, an additional 27 countries in the Americas have each reported from 1 to 68 AIDS cases.

B. Europe

Europe has reported 3,847 cases from 23 countries. The latest data summary from the WHO Collaborating Centre on AIDS in Paris reviewed the epidemiological situation as of 30 September 1986. The largest numbers of AIDS cases were reported from France (1050), the Federal Republic of Germany (675), the United Kingdom (512) and Italy (367). Additional countries reporting 100 or more cases included: Belgium (180), Denmark (107), the Netherlands (180), Spain (201) and Switzerland (170). As of the date of this report, 4 countries in the European Region reported no cases: Bulgaria, the German Democratic Republic, Hungary and the Union of Soviet Socialist Republics. Among the 3,251 adult cases among persons of European origin, 71 percent were homosexual or bisexual men, 13 percent were heterosexual intravenous drug users, 3 percent were homosexual men who were also intravenous drug users, 4 percent were haemophiliacs, 2 percent had received blood transfusions, 5 percent had none of the above-listed risk factors and information was not available for the remaining 2 percent of cases.

Most countries in Europe are now experiencing an epidemic of HIV infection. Current estimates of the total number of HIV-infected persons in Europe range from 500,000 to 1 million or more. Based on current trends, an estimated 25,000 to 30,000 AIDS cases are expected in Europe (cumulative) by the end of 1988.

C. Oceania

The cases thusfar reported from Oceania are all from Australia (364) and New Zealand (22) and are typical of "Western" epidemiological patterns.

D. Africa

No area of the world is more affected by HIV than Africa, in terms of the proportion of the healthy population already infected and probable numbers of AIDS cases. Central, Eastern and parts of Southern Africa are experiencing epidemic HIV infection and there is increasing evidence regarding a West African focus of additional human retroviral infections. In Africa, the epidemic of clinically recognizable AIDS appears to have started recently, between 1975 and 1980. The geographical scope and intensity of HIV infection in Africa is difficult to assess, due to limited infectious disease surveillance and laboratory serodiagnostic capabilities and lack of a widely accepted clinical case definition for AIDS. Nevertheless, a minimum estimate for the African continent includes 2 million HIV-infected persons and 10,000 to 20,000 cases of AIDS annually.

The proportion of healthy adults with serological evidence of HIV infection in the countries from AIDS-epidemic regions of Africa ranges from 6 to over 30 percent, although many of the studies have involved rather small and selected (often urban) populations. The annual incidence of clinical AIDS in some Central African cities is at least 500 to 1,000 per million population.

While the basic modes of HIV transmission in Africa are identical to those in the developed world (sexual, blood contact, perinatal), several important regional variations exist. The dominant mode of HIV transmission in Africa is sexual, involving heterosexual transmission (infected man to woman; infected woman to man) of the virus. Not surprisingly, the male to female ratio among AIDS cases or among HIV-infected persons is approximately 1:1, and HIV seroprevalence rates among African women prostitutes are quite high, generally ranging from 25 to 90 percent. Data from Nairobi, Kenya have demonstrated that once HIV is introduced into a heterosexually active population, rates of HIV infection may rise dramatically. Thus, in 1980-81, 4 percent of female prostitutes tested in Nairobi had antibodies to HIV; by 1985-86, 59 percent were seropositive.

The importance of blood transfusions for HIV transmission in Africa is suggested by the high proportion of infected (although healthy) blood donors, which reaches 5 to 18 percent in some areas. Therefore, persons receiving blood transfusions from these donors may face a 1:20 to a nearly 1:5 chance of becoming infected with HIV. While practices for collecting and transfusing blood vary widely throughout Africa, screening of donors for HIV infection is not usually performed and storage and processing facilities are often insufficient.

While intravenous drug use is virtually absent in most of Africa, the problem of HIV transmission through contaminated needles exists in other ways. Any needle or other skin-piercing instrument that becomes contaminated with the blood of one person and is then used, without proper sterilisation, to pierce the skin of another person can become a vehicle for HIV transmission. The problem in Africa particularly involves injections given for medical purposes, such as for treatment of malaria, fevers, diarrhoea or other common problems. While such injections are probably not a very efficient route for HIV transmission, persons receiving large numbers of injections, especially in peripheral, poorly equipped clinics, in para-medical or non-medical settings, may be exposed to and infected with HIV. Fortunately, current evidence suggests that HIV is not being spread through childhood vaccination programmes, in large part due to the longstanding and aggressive efforts to ensure clean needles and syringes in these vital public health programmes.

Since HIV is heterosexually transmitted, pregnant women are among those in Africa who are likely to be HIV infected, with resulting transmission of the virus to their children, either before, during, or shortly after birth. While the efficiency of mother-to-child spread is presently unknown, in areas of Africa where 10 percent or more of pregnant women are HIV seropositive, as many as 5 percent of all newborns may be HIV infected from birth. Paediatric AIDS, particularly difficult to recognize where malnutrition, respiratory and gastrointestinal infections are common, is an increasing problem in Africa.

Finally, despite important socioeconomic and environmental differences in household, occupational and other settings in Africa compared with Europe and North America, there is no epidemiological evidence to support casual contact transmission or transmission through mosquitoes or other insects.

E. Asia

In dramatic contrast to Africa, HIV has only started to appear in Asia. A small number of AIDS cases have been reported from Japan (21), Thailand (6), Hong Kong (3), India (2), China (1) and Taiwan (1). These cases have either been related to imported blood and blood products, or to sexual transmission among persons with high risk behaviours (female or male prostitutes). Serosurveys have thusfar demonstrated little or no evidence of HIV infection in general Asian populations, yet infections have occurred among members of particular risk groups. The current extent of HIV penetration into Asia is unknown; the opportunity for protection of Asia against widespread dissemination of HIV is evident and may be vital to the future of that continent.

F. The Natural History of HIV Infection

The eventual outcome of HIV infection remains unknown, as scientific knowledge about the natural history of HIV infection is limited to the 5-7 year observation period that has elapsed since AIDS was first described.

Three major HIV-associated outcomes have already been distinguished:

- AIDS
- AIDS-related illnesses
- HIV neurological disease

During a five year period, 10 to 30 percent of HIV-infected persons can be expected to develop AIDS. An additional 20-50 percent are likely to develop AIDS-related illnesses. The proportion of infected persons who will have HIV neurological disease (particularly dementia) is unknown, but an epidemic of progressive neurological disease among HIV-infected persons must be considered a realistic possibility.

Ultimately, the majority of infected persons may suffer a severe adverse health outcome or death associated with HIV infection.

G. Broad Impact of HIV Infection

The personal, social and economic costs of the HIV epidemic are enormous. Uncertainties regarding prognosis, along with fears and realities of exposure and ostracism lead HIV-infected but asymptomatic persons to experience higher levels of stress than AIDS patients themselves. The family structure and function is threatened both by infection and the loss of mothers and fathers. The social and economic fabric is dramatically affected by the epidemic of illness and death among productive 20-40 year olds, which is typical of AIDS epidemiology in industrialized and developing countries. In Africa, social and economic development may be threatened by the loss of a substantial proportion of 20-40 year old persons, particularly among the urban elites. The direct economic costs of AIDS are also enormous. For example, in the United States, the total cost of direct medical care for AIDS patients in 1991 is estimated to reach 16 billion dollars. In some Central African hospitals, 20 to 50 percent of adult patients on medical wards have AIDS or other

HIV-related conditions, placing an additional burden upon already limited health care systems. The combined impact of the HIV pandemic, of AIDS, AIDS-related diseases and neurological disease upon health care, insurance and legal systems, economic and social development and indeed entire cultures and populations is already extraordinary and will become increasingly profound.

Throughout the world, personal and public reaction to AIDS has been considerable. Fears of AIDS and stigmatization of different groups (homosexual men, haemophiliacs, Africans, Westerners, female prostitutes) have become common phenomena. However, this remarkable global response has been generated by only 30,000 AIDS cases in the United States, 4,000 cases in Europe, and a relatively few reported cases in many other countries. Individual, family, group and social tragedies are occurring regularly as a result of fears, most often unjustified, of HIV infection and its spread. Throughout the world, tremendous social pressures and tension are being generated by AIDS and AIDS-related concerns. Therefore, it must be anticipated that societal stresses resulting from the occurrence of 270,000 AIDS cases in the United States by 1991, 25,000 to 30,000 European AIDS cases by late 1988, and increasing worldwide infections may be correspondingly great. Proposed restrictions on HIV-infected workers and international travellers and the unfortunate tendency to blame "others" for HIV suggests some additional international aspects associated with the HIV pandemic.

Predictions of future epidemic trends are quite difficult. In addition, the pandemic appears to be progressing geographically as well as increasing in intensity in areas already infected. Further spread of HIV is certain to occur, for several reasons:

o Persons with HIV are likely to be infected for life; most will not develop any symptoms or evidence of illness for at least several years, during which time they may transmit HIV to others.

- HIV is spread sexually (from any infected person to his or her sexual partner), as well as through blood (transfusions, injections, skin-piercing instruments) and from mother-to-child. This combination of modes of transmission means that virtually all segments of the world's population have some degree of risk of exposure to HIV. In other words, once HIV is introduced into a population, spread is virtually inevitable.
- HIV is already disseminated throughout the world, even though regional differences in current intensities of infection are quite important.

WHO has estimated that 50 to 100 million persons may be infected with HIV worldwide by 1991; this provisional estimate will be conservative if HIV penetrates and spreads widely through South America and Asia.

II. Progress Towards Prevention and Control

A. Vaccine and Treatment

The prevention of HIV transmission would be facilitated by a safe and effective vaccine capable of preventing infection, or a therapeutic agent able to reduce or eliminate the infectiousness of already infected persons. However, despite rapid advances in the early phases of vaccine development, a vaccine suitable for large-scale use is considered highly unlikely to become available prior to the mid-1990s. In addition, a vaccine has never been made against a human retrovirus and several retrovirologists have raised the possibility that vaccines currently under development may not be protective.

A recent clinical treatment trial among AIDS patients found that azidothymidine (AZT) prolonged life and was associated with clinical and immunological improvement. There were, however, side-effects, including bone marrow suppression; longer-term benefits and risks of AZT treatment are currently unknown. AZT may nevertheless represent the first major step towards eventual development of safe and effective therapeutic agents. It is also possible that these agents could have a role in the treatment of asymptomatic HIV-infected persons, acting both to prevent progression to AIDS and reducing or eliminating their infectiousness. A very recent press report has suggested that the anti-viral drug ribavirin may prevent progression of HIV infection from an AIDS-related complex level (persistent generalized lymphadenopathy) to AIDS. However, this information, while encouraging, must be considered preliminary at this time.

Despite impressive technical and scientific advances, it is unlikely that a vaccine will become available to assist in controlling the pandemic of HIV infection during the next 5 years. Therefore, at least during this initial period, prevention will rely primarily upon educational interventions designed to promote sustained behavioural changes.

B. Recognition of the Pandemic

The magnitude of the HIV pandemic and its broad impact have been seriously underestimated and underappreciated. However, during the second half of 1986, a major shift of perspective and opinion has occurred in many North American, European and African countries. For example, in the United Kingdom, France, Italy and the United States, statements by prominent health officials and dramatically increased financial commitments for AIDS prevention programmes testify to a growing awareness of the scope of the HIV problem at national levels. An evolution in perspective regarding AIDS can be observed at the personal, group, social, national and international levels. The initial response to AIDS usually involves denial and an effort to minimize the problem, often through comparison of the numbers of AIDS cases with deaths from already well-described public health problems. Then, as the number of AIDS cases increases rapidly and estimates of the number of persons already infected with HIV in the population are developed and publicized, the HIV problem commands further attention. Finally, once the potential is recognized for HIV to involve major segments of the population, including those who may have previously considered themselves without risk, the epidemic nature and urgency of the HIV situation generate political committment and a willingness to act. Africa provides just one specific example of this generic evolution in perceptions about AIDS. AIDS was first discovered in Africa in late 1983. As epidemiological data became available during 1984 and 1985, the scope and intensity of the HIV situation in many African countries became clearer, yet AIDS was not recognized or accepted as a health priority. Then, in March 1986, at a WHO Regional meeting in Brazzaville (Congo), AIDS was publicly declared to be an important public health problem. Finally, at a WHO Regional Meeting on AIDS in Brazzaville in November 1986, representatives from 37 countries discussed AIDS openly and agreed that action to control the epidemic of AIDS in Africa had to be given the highest priority.

In May 1986, citing "intensive international interest and concern" about AIDS, the 39th World Health Assembly formally approved the creation of an AIDS programme within WHO. In November 1986, the Director-General of the World Health Organization announced that in the same spirit and with the same dedication which characterized WHO's global smallpox eradication programme, WHO was now committed to the more urgent, difficult and complex challenge of global AIDS prevention and control.

III. Global AIDS Prevention and Control

A. General Concepts

While the international HIV situation is dynamic, agreement exists on the fundamental concepts and principal components of global AIDS prevention and control.

The fundamental concepts include:

- HIV infection is an international health problem;
- Infection with HIV is an adverse health outcome of profound personal, family and social importance;
- HIV infections threaten the limited gains in health which have been achieved in several areas of the developing world;
- Neither vaccine nor therapy for widespread use is likely to become available for at least several years;
- The HIV global control effort will be long-term and will likely last beyond our generation;
- HIV prevention and control programmes must be integrated with primary health care;
- The HIV pandemic represents an unprecedented challenge to public health which mandates a response of unprecedented creativity, energy and resource.

The principal components of global AIDS prevention and control are:

- strong national AIDS prevention and control programmes
- international leadership, coordination and cooperation

B. The World Health Organization Special Programme on AIDS

The World Health Organization is a recognized international leader in public health, can draw upon broad existing expertise, and has established mechanisms for collaborating with countries throughout the world in the design, development, implementation and evaluation of national programmes. In the unprecedented effort for global AIDS prevention and control, WHO will draw particularly on its experience in global mobilization and coordination (smallpox eradication), research management (e.g., Tropical Diseases Research), development of active and effective programmes (e.g., Expanded

Programme on Immunization, Control of Diarrhoeal Diseases), the ability to work with non-governmental organizations and the private sector, and its longstanding collaborative relationships with Member States.

The Special Programme on AIDS has been created as the vehicle for the World Health Organization's critical role in global AIDS prevention and control. The Special Programme on AIDS will support the development of strong national AIDS prevention and control programmes, provide international leadership and assure global coordination and cooperation.

1. Objectives

The Special Programme on AIDS has two objectives:

- The primary objective is to prevent HIV transmission.
- The secondary objective is to reduce morbidity and mortality associated with HIV infection.

2. Support to National AIDS Programmes

The key components of national AIDS prevention and control programmes include:

a. political willingness to confront the HIV problem

b. creation of a National AIDS Committee, representing the health and broad social interests involved in the HIV problem

c. initial epidemiological and resource assessments

d. establishment of a surveillance system for AIDS and particularly for HIV infections

e. development of in-country laboratory capabilities

f. educational programmes for health workers at all levels

g. prevention programmes directed to the general public and to specific groups in the population

h. evaluation mechanisms based, to the extent possible, on HIV infection indicators

3. International Leadership, Coordination and Cooperation

The Special Programme on AIDS has certain global responsibilities and functions, including:

a. preparation and distribution of guidelines, strategy documents, manuals and other prototype materials

b. collection and analysis of data to describe current and future HIV infection trends, their social, economic and demographic impact, and implications for interventions

c. coordination, promotion and support to international biomedical, epidemiological, social, behavioural and operational research and development

d. development, promotion and support to design, implementation and evaluation of health promotion interventions which utilize behavioural change strategies and communication techniques

e. operation of active information exchange systems on scientific, legal, social and policy aspects of HIV

f. provision of training, organization of forums for international exchanges of scientific and technical information, development of criteria and international standards, and establishment of consensus on other issues of international scope and concern.

4. Strategies

The WHO Special Programme on AIDS has developed 9 broad strategies and has defined specific activities to be conducted within each strategy during 1987-89. However, the evolution of knowledge regarding HIV and techniques for preventing transmission or reducing the impact of HIV infection may stimulate changes in strategy or activities during this period.

The strategies include*:

a. prevention of sexual transmission
b. prevention of transmission through blood transfusion
c. prevention of transmission through blood products
d. prevention of transmission through injections and skin-piercing instruments
e. prevention of transmission through organ and semen donation
f. prevention of perinatal transmission
g. prevention of transmission from HIV-infected persons through use of therapeutic agents
h. prevention of HIV transmission through the development and delivery of vaccines
i. reduction of impact of HIV infection on individuals, groups and societies

(* strategies a-f are grouped according to transmission category - sexual, parenteral, perinatal)

5. Practical Issues and Considerations

The Special Programme on AIDS has taken up the challenge of providing rapid emergency assistance to Member States and to organizations working on AIDS crises and, at the same time, establishing the conceptual, technical and organizational foundation that is needed for effective medium and long term AIDS prevention and control programmes.

During 1987, therefore, both short-term support and long-term planning and strengthening will be provided to Member States. Immediate support, for example, is required for national educational programmes designed to prevent the sexual transmission of HIV; at the same time, WHO will prepare guidelines and prototype materials that can be used and adapted to create more effective programmes to prevent sexual transmission. The nature of the problem and the urgency with which it needs to be faced also means that during the next few years many of WHO's programme activities will need to be developed simultaneously or, certainly, not await the type of sequential development that might be anticipated with a less urgent type of problem.

The Special Programme on AIDS is already providing technical assistance and support to national activities in countries where there has been an epidemiological and political recognition of the HIV problem. This work urgently needs to be strengthened and broadened to assist countries already engaged in dealing with HIV. However, as better information becomes available in other countries with respect to the nature and magnitude of the HIV problem and as political willingness to confront AIDS in these countries increases, it can be anticipated that the level of support that will be requested of WHO will increase dramatically.

The budget estimates for 1987 are based on collaboration with the 30 to 40 countries, predominantly in Africa but also in Asia, the Middle East and the Americas, which have indicated active interest in immediate work with WHO. In many of these areas, the current health care system infrastructure may not permit more than selective interventions at this time. However, as developing countries in which the existing health care system infrastructure is capable of mobilizing national programmes begin to recognize the HIV problem, substantial additional financial resources may be required. Indeed, during 1987, one of the roles of the Programme will be to stimulate countries in assessing the HIV situation and in recognizing the need for a national prevention and control programme.

In order to take up this challenge the Special Programme on AIDS will need a first year staffing level and financial resources unprecedented in the Organization. The Organization's capacity to address personnel and infrastructure needs and, at the same time, its ability to attract the requisite funding to support the proposed programme of work, will determine whether the activities designated for 1987 can be accomplished.

IV. Summary

The HIV epidemic is global and involves both the industrialized and developing countries. It constitutes an urgent and unprecedented threat to global health. We are at an historic moment, at the beginnings of a global epidemic whose ultimate magnitude cannot be predicted. It is clear that action taken now will have greater impact than actions taken later. Therefore, a series of immediate priority actions, along with the development of a long-term strategy, are urgently needed.

National and international energies, resources, creativity and commitment will be required for global AIDS control. The World Health Organization has assumed its responsibility for leadership at the international level and is rapidly mobilizing the required internal and external resources. Through research, application of existing and improved technologies, and educational programmes leading to behavioural change, global AIDS prevention and control, although difficult and costly, will become possible.

* * *

The **Chairman**. Thank you very much for a very important and significant statement, one that is both dramatic and disturbing in terms of what is happening internationally in sections of the world.

You have referred in your testimony to the tendency to blame others, and we have also heard that on the agendas of some countries they are thinking about putting some restrictions in terms of world travel. Can you elaborate on both of those points?

Dr. **Mann**. Yes, sir. In terms of the stigmatization and the blaming of others, this appears to be part of the initial reflex reaction in almost every society to the appearance of this disease.

Anxiety is high and the desire to find someone to blame or a scapegoat is often high as well. Several countries have introduced proposals of different kinds to restrict international travel, and the World Health Organization, which is responsible also for the international health regulations, is taking a strong stand against the imposition of those kinds of restrictions, which we believe will have no beneficial effect in preventing the transmission of the virus.

The **Chairman**. What sort of restrictions? I think that is rather an unusual, to say the least, kind of requirement. What are we talking about, that you might not get entry into a particular country unless you have been tested? What sorts of things are we talking about?

Dr. **Mann**. Mr. Chairman, there have been proposals to restrict the travel of what you might call the routine traveler, the routine international short-term traveler. The proposal suggest that if that person cannot present a certificate showing that they are not infected with the virus, a certificate which not only could be easily fraudulently produced, but which in itself provides no guarantee of protection. They could be excluded.

In addition, there have been proposals to restrict the scholarships that could be given to students if the student is infected. And, finally, there have been restrictions proposed regarding long-term visa applicants, guest workers, if they wish to enter the country.

All of these are based on the false idea that by identifying infected people, you can somehow protect the home population. When this was proposed in the United Kingdom, however, it was pointed out that there are already 30 to 60,000 infected people in the United Kingdom and that the desire to exclude a few African students who might be infected appeared to not have major disease prevention significance.

The **Chairman**. This is being considered in what parts of the world, Western Europe?

Dr. **Mann**. These kinds of restrictions are being considered in a variety of parts of the world. There have been several initial suggestions proposed in the Americas which, thanks to the work of the Pan American Health Organization, have not been pursued.

There have been proposals in several parts of the Middle East in this regard, and also proposals in Europe. The European proposals have focused on students on long-term visa applicants.

In the United States, a proposal at one time had also been presented to address the same question.

The **Chairman**. How do you think your message can be effectively spread worldwide? Do you feel that there have been sufficient efforts to bring international representatives together to exchange AIDS information and to coordinate efforts?

Dr. MANN. Yes and no. There have been the major international conferences which the World Health Organization cosponsors, the first one in Atlanta, then in Paris, and then in Washington in June of this year.

And, in addition, we at WHO have had a series of meetings, and expect to have roughly 50 meetings during the next year on various aspects of international AIDS. I think it has taken a while for organizations and for people to realize just how broad the scope of this problem is, and I think in the next year we are going to hear a lot more about the social and economic impact rather than just the limited health impact in international forums.

The CHAIRMAN. About a month ago, the World Health Organization announced its plan to combat AIDS. Could you briefly summarize the plan?

Dr. MANN. The essence of the program, Mr. Chairman, involves the development of strong national AIDS prevention and control programs. Every country in the world needs this kind of program that starts by assessing the scope of the problem and then develops a series of concrete activities for which WHO has established the blueprint on how to proceed and what sort of steps are necessary.

And these, of course, include such issues as the surveillance aspect, the laboratory capability, the education and training of health professionals, and then the prevention programs to prevent sexual transmission, transmission through blood and blood products, and transmission from mother to child.

These are the key components of what every country in the world needs, but for which many countries need tremendous support in order to be able to implement. In some central African countries where AIDS is a severe problem, the annual health budget per capita is less than one dollar.

In those situations, without the addition of external aid, an AIDS prevention and control program is not a possibility.

In addition, there is a need for international leadership and coordination because many of these issues, such as the international travel issue, require international consensus, and the strongest force we have, in a sense, is the moral suasion that comes from the agreement of the best scientific minds in the world to address a particular issue.

If those minds say that there is no danger for an AIDS virus-infected person to travel on an aircraft, then we believe that the moral force of that argument will carry.

The CHAIRMAN. What else do you think that the United States ought to be doing as far as its role internationally?

Dr. MANN. Well, certainly, Mr. Chairman, we are looking for support from the United States, for significant support both in terms of the technical resource, people, and the financial resource to be able to implement the 1987 action plan and the plans beyond that.

It is important that this kind of international AIDS control effort have the resource that is required, a resource that will grow rapidly as the awareness and ability of countries to deal with the problem increases.

The **Chairman**. The World Health Organization is facing financial difficulties. Could you tell us, in terms of this particular program, the battle internationally on AIDS, what are you talking about in terms of their effort?

The World Health Organization has been very, very involved in the past in eradicating a variety of different kinds of diseases, scourges, plagues, others. Now, they have identified an action program internationally. What is its estimated cost?

Dr. **Mann**. The estimated cost for 1987 is $43 million.

The **Chairman**. In '88?

Dr. **Mann**. We will know in about four months, with some experience of '87, what '88 will cost. You must realize, Mr. Chairman, that in this area the key unknown variable is the extent to which countries will indeed take on the challenge of global AIDS control.

That figure could easily increase ten-fold within two years.

The **Chairman**. Well, what is your estimate of your budget for 1990?

Dr. **Mann**. The 1990 estimate for the budget for global AIDS control approaches $1 to $1.5 billion.

The **Chairman**. And you professionally and scientifically believe that that kind of resource is necessary to battle this internationally?

Dr. **Mann**. Without question, and that includes the requirement for the non-governmental organizations and the myriad of other organizations to include their work, and that work is not included in the total sum.

The **Chairman**. And what kind of pledges do you have up to this point to try and give you some kind of assurance that the world community is going to take this kind of plan seriously?

Dr. **Mann**. Well, first, Mr. Chairman, I must say that the response to AIDS has changed dramatically in one year. Six months ago, on the basis of a $12 million request for funding for two years for the World Health Organization AIDS program, we received $9 million of that $12 million from seven countries, of which $2 million came from the United States.

Now, we are going back to those countries and saying our assessment of the problem is such that $43 million is needed in 1987 alone, and all of those countries without exception have spoken positively of the need to do this kind of program and of the need for the additional resource.

Now, whether the resource that would be available in 1990 or 1991 will truly become available, I think, depends entirely on what happens and on the perception. But when we look at the fact that two years ago, people did not even realize that AIDS was a global problem and that now we understand the true global magnitude and the threat it represents, I think that in one year from now, Mr. Chairman, I could speak in front of this Committee and tell you about the dramatic increase in availability of funding as a result of increased awareness.

The **Chairman**. I hope you are right.

How many people do you now have working on this with regard to WHO? How many are assigned to this?

Dr. **Mann**. The WHO AIDS program, which started in June of '86, started with one professional, increased to three, and Dr.

Mahler has indicated that I will have 15 professionals working on the staff as of later next week.

In other words, this is being done with the real rob Peter-to-pay-Paul principle. This is being done by taking people on a short-term basis from other important programs within WHO and establishing the critical mass of approximately 15 professionals that will allow us to initiate and implement the 1987 action plan.

The **Chairman**. Well, for something that really is a global threat and something which we are going to eventually end up investing a good deal of resources both from a research and educational point of view and billions of dollars in terms of care, and to recognize the international and global scope of this whole challenge, we are starting off internationally with three professional people.

We do not question your leadership and your commitment and dedication or Dr. Mahler's at WHO, but it is certainly an effort that must be and should be supported, and hopefully would be, and we will certainly work with you here in the Congress to try and gain that support.

Dr. Mann, one month ago, the world was surprised with the news that a vaccine trial had started in Zaire. What can you tell us about that trial?

Dr. **Mann**. Mr. Chairman, I can tell you unfortunately little of a scientific nature about that trial. This trial was brought to our attention, actually, by the media, and most of what the World Health Organization knows about this trial, it has read in the newspapers, French and American.

What appears to have happened according to these reports is that a vaccine trial has indeed been underway in Zaire for a period of at least several months, and we are eagerly awaiting the scientific information that will allow us to assess whether this trial contributes or does not contribute to the ultimate development of a vaccine available for large populations.

The **Chairman**. Well, given the need for international coordination, is it not unusual for a secret vaccine trial to be underway?

Dr. **Mann**. Well, I think it is extremely unfortunate. In fact, the World Health Organization had a meeting in mid-December where we brought five American, four European and four African experts together and agreed that it is critical in this area that the clinical trials of AIDS vaccine, because they are of such importance to the entire world, be done in a scientifically open manner involving the international scientific community and in a socially and ethically acceptable manner.

The real disaster would be if a vaccine were inadequately tested somewhere, pronounced to be effective in the media, but yet not effective or not assessable on the basis of information that was developed.

That would create a disaster because the pressure to use the vaccine would be intense and the unfortunate consequence could ensue where a vaccine that does not protect or even hurts could be used in millions of people, and that could even delay the ultimate development of a vaccine that would truly protect.

So we are strongly committed to the need for international collaboration and communication in the vaccine development area.

The **Chairman**. Well, I think you have talked about it briefly, but what is really the danger of an individual, secret trial that does not have the larger research community, both in terms of progress on the issue and for the individual as well?

Dr. **Mann**. For the individuals involved, there is always the concern about the human rights; there should be the concern about the human rights and the ethical standards under which this vaccine would be tested.

And I am sure that other people who have spoken to you this morning could speak quite eloquently about the need for ethical safeguards in vaccine field trial development, particularly with AIDS vaccine.

The other danger is that a vaccine field trial might not be adequately well designed or adequately well conducted. These are difficult to perform. When we get to the final pay-off, which is the question of does a vaccine work, does it protect, that is going to be an extraordinarily difficult process which may take several years to figure out, to decide, on the basis of scientific evidence.

And if one proceeds too rapidly——

The **Chairman**. Wait a minute. Just on this point, you mean from the time the vaccine is actually developed until the time that you have information that would indicate its effectiveness?

Dr. **Mann**. That it worked, yes, sir.

The **Chairman**. It may be what? How long did you say?

Dr. **Mann**. We would estimate it could be as long as several years.

The **Chairman**. Several years?

Dr. **Mann**. That is right, and that just emphasizes and underlines the complexity of the work. It is not easy to conduct a vaccine field trial and efforts by people who may not be in contact with the real experts internationally in this field could conduct a trial with good faith, but with inadequate scientific credibility, and that is where we all could be the losers.

The international scientific community offers the best chance to get the best minds working on this problem.

The **Chairman**. You are concerned that it may create false hope and false answers?

Dr. **Mann**. False hope, false answers, and if we imagine the scenario where a vaccine that did not work was proclaimed as a vaccine that worked and was used by people who then abandoned their safer practices, believing that they were protected, I think the importance of that kind of misinformation is clear.

The **Chairman**. Is there anything additional that you can tell us about the French test? I mean, have you made any kind of medical assessment as to its effectiveness?

Dr. **Mann**. Mr. Chairman, we have no facts. We know that a vaccine is being used and we do not really even know the numbers of people involved. We do not know the manner in which those people were selected. We do not know what tests have been used to determine the effectiveness of the so-called vaccine.

I think it must be considered to be highly preliminary and that our best interests lie in sharing of the information as rapidly as possible.

The **Chairman**. Given the great interest in the development of the vaccine both in the private and public spheres in this country and in other countries, is it realistic to expect coordination in vaccine development and testing?

Dr. **Mann**. It will be difficult in this area because this is AIDS and because of the intensity of public and professional involvement with this subject. On the other hand, the World Health Organization has a track record. We have a track record in vaccine development, we have a track record in research management, we have a track record in establishing standards and guidelines for international use.

I think that we must make this effort, which ultimately boils down to an effort of voluntary participation by vaccine manufacturers, scientists and others throughout the world to realize that the benefits of collaboration benefit the whole world and that this problem is too important to leave to any one laboratory or to any one research facility.

However, we may not succeed, but the alternative to trying is potential chaos in this area.

The **Chairman**. Well, do you have an estimate as to the number of people that, say, in 1991 worldwide would be infected? We have heard figures up to close to 150 million people.

Dr. **Mann**. The World Health Organization estimate—the one that you quoted, in fact, in your opening remarks—is 50 to 100 million.

The **Chairman**. I see.

Dr. **Mann**. And this is speculative.

The **Chairman**. That is right.

Dr. **Mann**. As I suggested earlier, if it enters the Asian populations, 100 million is an excessively conservative figure.

The **Chairman**. I see. I just want to, for our audience here and those who are watching, to mention about the World Health Organization. They have been perhaps more responsible for the eradication of smallpox than any other organization, any group in the world, and they have made very significant progress in malaria, typhus, yellow fever, rabies, and others.

So they are speaking from a track record of profound experience, and I think when they warn us about the global implications of this, we ignore that at our own risk. That has an enormous and significant importance to us as a people.

Senator Adams.

Senator **Adams**. Thank you, Mr. Chairman. I have no questions. I appreciate the testimony of the witness, and I apologize to the Chairman. I have been over in the nuclear threshold test ban treaty area. Otherwise, I would have been here with you.

The **Chairman**. Thank you very much.

We are delighted to have Dr. St. John here. I imagine that Dr. Mann, when he was talking about the global implications, was talking about Central America and the hemisphere as well, and we welcome and thank you for joining us here today.

Thank you very much, gentlemen.

Dr. **Mann**. Thank you very much.

The **Chairman**. Our final panel will focus on the development of a vaccine. I would like to welcome Dr. Anthony Fauci, who is the

Director of the National Institute of Allergy and Infectious Disease and AIDS Coordinator for the National Institutes of Health; Dr. David Martin, the Vice President for Research of the biotechnology company Genentech; and Dr. Samuel Katz, of Duke University, a member of the expert Institute of Medicine Panel on Vaccine Development.

There are many important issues which we must address so a vaccine will be available to the public in time to help protect the world's populations from the AIDS plague, and I think that our panel here this morning can provide for this Committee and hopefully for the public an update of where we are medically in terms of vaccine development.

We will start with Dr. Fauci.

STATEMENT OF ANTHONY S. FAUCI, M.D., DIRECTOR, NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES, AND COORDINATOR OF AIDS RESEARCH, NATIONAL INSTITUTES OF HEALTH, WASHINGTON, DC; DAVID W. MARTIN, JR., M.D., VICE PRESIDENT, RESEARCH, GENENTECH, INC., SAN FRANCISCO, CA, ACCOMPANIED BY BRYAN CUNNINGHAM, VICE PRESIDENT AND GENERAL COUNSEL, GENENTECH, INC., SAN FRANCISCO, CA; AND SAMUEL L. KATZ, M.D., PROFESSOR AND CHAIRMAN, DEPARTMENT OF PEDIATRICS, DUKE UNIVERSITY SCHOOL OF MEDICINE, DURHAM, NC

Dr. FAUCI. Mr. Chairman, members of the Committee, I am here today to discuss the research activities of the National Institutes of Health, (NIH), related to the development of a vaccine for the prevention of AIDS and AIDS-related diseases.

I have submitted my written opening statement for the record. I would now like to summarize briefly the salient features of that statement.

As soon as it was recognized that AIDS was caused by a specific virus that attacks the human immune system, the NIH aggressively pursued the development of a vaccine to prevent this devastating disease.

At the present time, vaccine development and research is being supported extramurally by NIH as well as in the NIH intramural program. The NIH has obligated a total of $20,518,000, total, from 1984 to 1986 to vaccine development efforts.

It is estimated that $26,677,000 will be obligated in fiscal year '87, and the President's budget for fiscal year '88 reflects $42,054,000 for vaccine research. These sums do not include the great deal of basic research funded by and at the NIH that forms the foundation for and that is applicable to vaccine development.

In this regard, it is important to point out that the advances we have made toward developing a vaccine are due to the previous investments in basic research and the resulting knowledge gained in the areas of virology, molecular biology, microbial genetics and immunology.

Despite these advances, a great deal of work needs to be done before an effective vaccine will be available. Nonetheless, concrete steps are already being taken in vaccine studies.

A number of candidate AIDS vaccine preparations have been made using a variety of scientific approaches. The specific details of several of these approaches and the institutes involved in the execution and/or support of them are described in my written statement.

In order to expand further the scope of investigators involved and the types of approaches used, the NIH will establish in fiscal year '88 several National Cooperative Vaccine Discovery Groups that will consist of multi-institutional, multi-disciplinary research teams to develop creative and targeted approaches to vaccine development.

This program will encourage the collaboration of academic and industrial organizations. In addition, as a step toward increasing the NIH intramural capabilities in AIDS vaccine development, an intramural vaccine development unit was established by NIAID in fiscal year 1986.

After candidate vaccines have been shown to be safe and immunogenic in the laboratory and in animal testing, they will become the responsibility of the NIAID, the National Institute of Allergy and Infectious Diseases, for clinical evaluation in humans.

NIAID currently supports six vaccine evaluation units specifically designed to conduct phase I and phase II safety and antigenicity testing of vaccines in humans. Several of these units will be involved in AIDS vaccine testing and are now preparing for the time when candidate preparations become available.

Those units to be involved in AIDS vaccine testing will be expanded to allow them to respond to this additional need while maintaining their commitments to other important vaccine testing efforts.

It is likely that phase I studies aimed at determining safety and immunogenicity of a candidate vaccine may be initiated in 1987 or the beginning of 1988. Coordination of NIH scientific efforts in vaccine development is handled through a variety of mechanisms.

The CHAIRMAN. If I could just ask you, what are the numbers you are talking about that may be tested on?

Dr. FAUCI. When you have phase I studies, they are, relatively speaking, small numbers. You are talking of approximately a hundred people which then in phase II go into a thousand or so and in phase III, larger numbers.

The CHAIRMAN. Right.

Dr. FAUCI. Coordination of NIH scientific efforts in vaccine development, as I mentioned, is handled through a variety of mechanisms. There is a great deal of coordination of efforts that occurs through the usual informal scientist-to-scientist interaction between NIH institutes, other Public Health Service agencies, private industry, and academic institutes.

The NIH AIDS Executive Committee, which is made up of directors of the NIH components with AIDS research responsibilities, meets regularly twice a month to coordinate administrative, fiscal and research efforts.

The committee is co-chaired by the Director of the NIH and myself. In addition, I have established an NIH-wide AIDS scientific vaccine committee made up of intramural scientists actively engaged in AIDS vaccine research.

Exchange of information on vaccine development with other Public Health Service agencies is facilitated by the PHS AIDS Vaccine Development and Therapeutic Intervention Subgroup of the PHS Task Force on AIDS that meets regularly.

In summary, the NIH has responded to the need for a vaccine to prevent AIDS and AIDS-related disease through the development of a number of basic and applied research efforts both within its intramural laboratories and through extramural support of academic and industrial organizations.

Important advances have been made. However, despite these rapid advances, given the nature of the AIDS epidemic and other considerations which I will be happy to discuss with you during the question period, even if the preparations now under investigation prove to be safe and effective, it is likely that it will take a number of years until a vaccine is available for widespread use.

The CHAIRMAN. Can you just elaborate on that? How many years are you talking about?

Dr. FAUCI. You are talking about from five to eight years. If you talk about phase I studies, they go from three to nine months; phase II, anywhere from a few months to 36 months; and phase III, which involves larger, widespread, multi-center, controlled trials, will take up to five or eight years.

So we do not expect, if we do have a vaccine, that it will be available for widespread use well into the 1990s.

This concludes my remarks, Mr. Chairman.

[The prepared statement of Dr. Fauci follows:]

STATEMENT BY

ANTHONY S. FAUCI, M.D.

DIRECTOR

NATIONAL INSTITUTE OF ALLERGY AND INFECTIOUS DISEASES

AND

COORDINATOR OF AIDS RESEARCH

NATIONAL INSTITUTES OF HEALTH

PUBLIC HEALTH SERVICE

DEPARTMENT OF HEALTH AND HUMAN SERVICES

BEFORE THE

SENATE LABOR AND HUMAN RESOURCES COMMITTEE

JANUARY 15, 1987

Mr. Chairman, members of the Committee. I am here today to discuss the research activities of the National Institutes of Health (NIH) related to the development of a vaccine for the prevention of AIDS and AIDS-related diseases. I will report on the status of AIDS vaccine development efforts and on plans for future research initiatives.

INTRODUCTION

As soon as it was recognized that AIDS was caused by a specific virus which attacks the human immune system, the NIH agressively pursued the development of a vaccine to prevent this devastating disease. At the present time, vaccine development research is being conducted in NIH intramural research laboratories and supported at outside institutions by the National Institute of Allergy and Infectious Diseases (NIAID), the National Cancer Institute (NCI), and the Division of Research Resources (DRR). The NIH has obligated $20,518,000 from FY 1984 to FY 1986 on vaccine development efforts. It is estimated that $26,677,000 will be obligated in FY 1987, and the President's budget for FY 1988 reflects $42,054,000 for vaccine research. These sums do not include the great deal of basic research funded by and at the NIH that forms the foundation for, and that is applicable to, vaccine development. In addition to these in-house activities, many NIH intramural scientists and extramural scientists supported by the NIH are collaborating closely with industry in these vaccine development efforts. A number of NIH intramural scientists are collaborating with a variety of industrial organizations and academic institutions by sharing scientific expertise and research materials. Most of the initial efforts on vaccine were focused in the NIH intramural program because the virus was isolated in those laboratories and because it is possible to change the focus of research efforts more quickly in intramural laboratories. There is a steady shift in the direction of extramural involvement and a number of extramural efforts for vaccine development will be described later.

I think it is important to point out that the advances we have made toward developing a vaccine are due to the previous investments in basic research and the resulting knowledge gained in the areas of virology, molecular biology, microbial genetics and immunology. The foundation of basic research, coupled with new biomedical technologies, have enabled us to learn more about the nature of the AIDS virus, its component structures and their functions, and its mechanisms of pathogenesis in a shorter period of time than has been the case with any other infectious disease.

Despite these advances, a great deal of work needs to be done before an effective vaccine will be available. We need to define clearly the role of the human immune system in the pathogenesis of AIDS. We must have a better understanding of the immune mechanisms that are able to prevent either the initial viral infection or the progression of an asymptomatic infection to full-blown AIDS. We must understand the reasons for differences in susceptibility to infection from individual to individual.

Through the technologies of molecular biology, we will have greater insight into the antigenic variation of various components of the virus in order to identify those with most potential as candidate immunizing agents. We are supporting a large number of intramural and extramural research projects directed toward these basic research goals.

APPROACHES TO THE DEVELOPMENT OF CANDIDATE VACCINES

A number of candidate AIDS vaccine preparations have been made using a variety of scientific approaches. These approaches include the use of whole killed AIDS virus, subunit preparations extracted from the virus, recombinant DNA-produced antigens, synthetic antigens, and vaccines produced by the insertion of AIDS virus DNA into a live vaccinia virus vector. Specific efforts underway include the following:

* Scientists at the NCI have isolated purified fractions of the viral envelope glycoprotein. One such preparation, called the gp120 subunit, has been inoculated into goats, horses and rhesus monkeys. These animals produced antibodies to this fraction that were capable of neutralizing the AIDS virus in laboratory tests. Both the natural and the genetically engineered pieces of gp120 are being tested in chimpanzees to assess whether actual

infection with the AIDS virus can be prevented in vaccinated animals.

- Scientists at the NIAID have inserted the region of the AIDS virus DNA that codes for the expression of its envelope proteins into vaccinia virus. In collaboration with the NCI, NIAID investigators have inoculated Macaque monkeys with this recombinant vaccinia vector preparation and antibodies have been produced that also neutralize the AIDS virus in laboratory tests.

- In addition, the NIH is also supporting research that has produced two synthetic peptides containing amino acids that are analogous to the gp120 and gp41 regions of the AIDS virus envelope glycoprotein. Antisera from rabbits inoculated with these peptides were capable of neutralizing AIDS virus infectivity in laboratory assays. The synthetic peptide which corresponds to the gp41 region is currently being evaluated in chimpanzees. Considerable intramural and R & D contract supported efforts are being focused on the development of these types of synthetic vaccines. Some of these preparations are being tested for safety and antigenicity in laboratory and animal studies. Depending on these results, phase I studies in humans will be initiated at the appropriate time.

Many of these viral vaccine preparations, particularly the small molecular weight antigens such as the subunit fractions and the synthetic peptides, are only able to elicit a weak antibody response when injected into animals. In order to increase the antigenic response, investigators have injected these antigens in combination with other agents called adjuvants. While a number of adjuvants can be used in animals, only one, alum, is approved as safe for use in humans. Therefore, the NIH will be supporting research projects to develop additional adjuvants as well as to explore other procedures for the safe potentiation of the human immune response to these small antigens.

GENERAL VACCINE DEVELOPMENT EFFORTS

At the present time, no one knows which of these various approaches will provide the best vaccine candidates. Therefore, it is important that all scientifically sound approaches be pursued. To further expand the numbers of investigators involved and the types of approaches used, the NIH will establish in FY 1988 several National Cooperative Vaccine Discovery Groups based on the model of the National Cooperative Drug Discovery Groups, that were extablished to provide innovative scientific approaches to targeted drug development. Likewise, the National Cooperative Vaccine Discovery Groups that consist of multi-institutional, multi-disciplinary research groups will develop creative and targeted approaches to vaccine development. This program will encourage the collaboration of academic and industrial organizations in the use of their scientific talents and resources to address AIDS vaccine development.

As a step toward increasing the NIH intramural capabilities in AIDS vaccine development, an intramural Vaccine Development Unit was established by the NIAID in FY 1986. The capabilities of this unit will be expanded this year to encompass a full range of vaccine development activities including basic research on the molecular biology of the virus and the host immune response. In addition, a concerted effort will be undertaken to develop appropriate animal models for the evaluation of candidate vaccines. To support this latter effort, a high quality animal containment facility will be a component of this unit.

The availability of appropriate animal models for the testing of candidate vaccines is a particularly urgent need. At the present time, the chimpanzee is the only model of human AIDS virus infection that can be used for the evaluation of candidate vaccines and therapeutic agents. Although the chimpanzee does not develop the disease, an infection can be established in this primate, and valuable information on the immune response to the virus as well as on the potential of various candidate vaccine preparations can be obtained. While there are other primate models that may be of some value in vaccine and treatment studies, they involve disease caused by a related primate virus not identical, to the human AIDS virus. Considerable intramural and extramural research efforts are being directed, through several individual NIH components, toward the further refinement of the chimpanzee model and toward the development of an alternative model.

After candidate vaccines developed by the NIH have been shown to be safe and immunogenic in laboratory and animal tests, they will become the responsibility of the NIAID for clinical evaluation in humans. Candidate vaccines will be evaluated through R & D contract supported institutions in collaboration with intramural scientists, other NIH Institutes and other appropriate PHS agencies. The NIAID has a great deal of experience in the development and evaluation of vaccines against a large number of infectious agents. It currently supports six vaccine evaluation units specifically designed to conduct phase I and phase II safety and antigenicity testing of vaccines in humans. Several of these units will be involved in AIDS vaccine testing and are now preparing for the time when candidate preparations become available. Those units to be involved in AIDS vaccine work will be expanded to allow them to respond to this additional need while maintaining their commitments to other important vaccine testing efforts.

PHASES IN AIDS VACCINE CLINICAL TESTING

As mentioned, these units are primarily designed for early vaccine testing. The first step in vaccine testing in humans is referred to as phase I. In phase I studies, the primary purpose is to look for toxicity or gross adverse side effects of the vaccine, gain some information on its immunogenic potency in humans, and establish a proper dose level for further studies. Phase II studies involve larger numbers of subjects and provide more information on safety and immunogenicity. These phase II studies confirm the proper dose levels and may provide some preliminary data on the possible effectiveness of the vaccine in preventing disease. After a vaccine has completed phase I and II testing, it is moved to phase III studies that involve large numbers of volunteers. These studies are often multi-centered, and are usually designed as randomized, placebo-controlled trials. These phase III trials provide the statistically significant data on the efficacy of the vaccine that is necessary before the vaccine can be made available for general use. **It is likely that phase I studies of a candidate vaccine may be initiated in 1987 or the beginning of 1988.**

The AIDS Program of the NIAID sponsored a workshop on AIDS vaccine development in July of 1986 which addressed the status of various approaches to vaccine development and began discussions on the design of safety, antigenicity and efficacy studies of AIDS vaccines. The PHS will be holding a meeting in March of 1987 for further discussions on the design of clinical trials and to establish the criteria that should be met by vaccine preparations to be considered for human trials.

COORDINATION

Coordination of NIH scientific efforts in vaccine development are handled through a variety of mechanisms. A great deal of coordination of efforts occurs through the usual informal scientist-to-scientist interaction between NIH Institutes, other PHS agencies, private industry and academic institutions. The NIH AIDS Executive Committee, which is made up of Directors of NIH components with AIDS research responsibilities meets twice a month to coordinate administrative, fiscal and research efforts. In addition, I have established an NIH-wide AIDS Scientific Vaccine Committee made up of intramural scientists actively engaged in AIDS vaccine research. This Committee meets regularly to discuss scientific approaches to vaccine development and results of current research as well as to plan new experiments. Members of NIAID's extramural AIDS Program staff attend these meetings in order to be aware of the status of vaccine research and to plan for future testing through extramural facilities.

Exchange of information on vaccine development with other PHS agencies is facilitated by the PHS AIDS Vaccine Development and Therapeutic Intervention Subgroup of the Public Health Service Task Force on AIDS. This subgroup also meets on a regular basis, and each agency involved in research on AIDS vaccines provides updated reports on its work and discusses future plans. Further PHS coordination comes from meetings of the main PHS Task Force itself that meets twice a month.

SUMMARY

In summary, the NIH has responded to the need for a vaccine to prevent AIDS and AIDS-related disease through the development of a number of basic and applied research efforts both within its intramural laboratories and through extramural support of academic and industrial organizations. Important advances have been made in better understanding of the pathogenesis of the disease, the nature of the causal agent, and factors important in the immune response of the host. The rapid advances made in understanding the biology and molecular biology of the AIDS virus have led to concrete steps being taken toward the development of a vaccine through the preparation of several candidates that are in various stages of preclinical testing. Despite these rapid advances, given the nature of the AIDS epidemic, even if the preparations now under investigation prove to be safe and effective, **it is likely that it will take a number of years until a vaccine is available for widespread use.**

Mr. Chairman, members of the Committee, this concludes my prepared statement. I will be happy to answer any questions you have.

The **Chairman**. Could we have Dr. David Martin?

Dr. **Martin**. Yes, thank you, Mr. Chairman. My name is David Martin. I am a physician and geneticist, and Vice President and Director of Research of Genentech. With me is Bryan Cunningham, who is Vice President and General Counsel of Genentech.

Genentech is a leading biotechnology company committed to the research, development and commercialization of pharmaceutical products made through recombinant DNA technology.

Genentech is one of the biotechnology companies actually pursuing development of an AIDS vaccine. I appreciate the opportunity to share with you the promise and the frustrations of our efforts in this area.

A major hope in the struggle against AIDS is that development of a vaccine will be possible. The consensus of experts, including those at the WHO and the National Academy of Sciences, is that even if the scientific and non-scientific issues which cloud the development of an AIDS vaccine can be resolved, a vaccine is five or more years away.

Although a vaccine may be years away, this should not detract from the tremendous strides of the scientific community that you have heard about earlier this morning, nor should it dash any hopes for a vaccine.

Perhaps the major scientific obstacle involved in producing an effective AIDS vaccine is the virus variation problem. This problem stems from the fact that there exist multiple strains of HIV, or the AIDS virus, with immunologically distinct surfaces.

This enables the virus to evade an immune response because the immune response—for example, one generated by vaccination—which eliminates one type of virus may be less effective or ineffective in eliminating a virus with a slightly different surface component.

A similar situation exists in the case of polio, where there are three immunologic-distinct forms of the virus. All three types of viruses are included in a polyvalent vaccine. This vaccine has been spectacularly effective and it is obvious that a similar polyvalent vaccine for AIDS might protect individuals against the various types of the virus.

Unfortunately, the number of HIV types—that is, serotypes—is completely unknown at this time. Federal efforts should support and expedite the ongoing research efforts.

First, Congress should provide increasing funding to greatly enhance and fully support the NIH and other governmental and private agencies who are conducting serotyping of the AIDS virus. The same serotyping program which was done for polio is essential for the development of an AIDS vaccine. The technology for this serotyping currently exists.

The results of this typing will allow the various investigators working on an AIDS vaccine to choose the genes from the appropriate viral isolates for inclusion in a polyvalent vaccine in order to provide broad protection against the different types of AIDS virus.

Secondly, we urge this Committee to take steps to develop a central repository for viral isolates and patient sera so that they are readily available to all qualified scientists.

The powerful tools of biotechnology have much to offer in the development of vaccines, particularly in connection with an AIDS vaccine. Genetically-engineered vaccines based on portions of the recombinantly-produced surfaces of AIDS viral envelope are inherently much safer than conventional vaccines which used weakened or killed vaccines.

Recombinantly-produced fragment merely mimics a portion of the virus in order to trigger an immune response. Absolutely no one will develop an AIDS infection from this type of vaccine.

No vaccine, however, is a hundred percent safe. It will not be until after the widespread use of an AIDS vaccine that the infrequent adverse effects will be identifiable. Testing of an AIDS vaccine has its own unique problems. There are no good animal models.

Because the HIV affects certain non-human primates, it does not generate an AIDS in those animals. Only direct test on humans will suffice, and the direct test will clearly raise many social, ethical and political questions in the determination of whether a vaccine will be effective.

Because of the long latency period of HIV in humans after infection, it may take, as Dr. Fauci has said, many years to determine whether it effectively prevents AIDS.

The Institute of Medicine conference in March of 1986 found that promising research results are not developed into products because of, number one, the enormous expense of clinical trials; number two, the unknown market size, particularly with adult vaccines which are not mandated by the States; and, number three, the potential for large and unpredictable awards in product liability cases where the manufacturer has properly made a vaccine which has an inherent and unknown risk, one that cannot be avoided.

The Institute of Medicine has correctly identified the barriers to vaccine development. The uncertain legal environment has had tangible adverse effects on vaccine manufacturers. It has discouraged the manufacturer in innovation of vaccines.

Some pharmaceutical manufacturers have chosen to opt out of the vaccine business altogether. The remaining manufacturers have been forced to reflect the increased cost in their prices.

Last fall when Congress considered the childhood vaccines bill, the number of manufacturers had dwindled to one manufacturer of polio vaccine, one manufacturer of vaccines for measles, mumps and rubella, and two DPT vaccine manufacturers.

In fact, in May of 1986, the two manufacturers of the DPT vaccine announced tremendous price hikes to cover the cost of lawsuits. One of the manufacturers, which had priced a dose of vaccine in 1982 at 11 cents per dose, was reportedly charging $11 per dose after June 1986 to cover the costs of litigation through self-insurance.

The same disincentives for manufacturing childhood vaccines exist for developing an AIDS vaccine. In addition, there are other obstacles to the development of an AIDS vaccine.

Unlike the childhood vaccines whose widespread use identified adverse side effects, we cannot accurately know or guess what side effects will be associated with an AIDS vaccine.

Unlike the childhood vaccines which the States make mandatory for each child, we do not yet know whether or when the government will make an AIDS vaccine mandatory.

The question of who will use the vaccine is critical to answer for purposes of commercialization, but it has even more significant health consequences. From a public health point of view, there are a number of reasons why the government should make an AIDS vaccine, once developed and proven safe, compulsory.

First, the most important consideration is that the current epidemiology of AIDS in the United States and its prevalence in the identified high-risk groups such as homosexual men and IV drug abusers most likely reflect the transmission of the virus five or more years ago.

Five years from today, we may well see an entirely different epidemiologic picture for HIV infection with a much greater prevalence in the general heterosexual population.

Indeed, we already know from the epidemiology of HIV infection in Africa that at least certain HIV strains can be spread through the heterosexual population. For this reason, the vaccination of the general population at the earliest possible date is essential to prevent anything remotely similar to the widespread heterosexual epidemic now in progress in several African nations.

Secondly, there is absolutely no way to guarantee that the nation's blood supply will remain entirely safe with respect to HIV transmission. Generalized vaccination of the heterosexual population is the only way to reduce the risk that contaminated blood is not inadvertently administered to unprotected individuals.

Thirdly, we cannot afford to allow HIV to become endemic in the way that hepatitis B has. Currently, there are over two million carriers of hepatitis B in the United States and nearly 200 million in the People's Republic of China.

As has happened for hepatitis B, once a significant number of women of child-bearing age are infected with HIV, the infection may become endemic because it is frequently passed to the children of such mothers. If we do not intervene now, we may be faced in the future with a widespread, chronic, endemic infection and a large pool of carriers.

Fourthly, generalized vaccination programs are responsible for the remarkable successes of the smallpox and the polio immunization/eradication programs which you heard about a few moments ago.

Vaccines targeted at high-risk groups without compulsion, such as the hepatitis B vaccine, have failed to prevent an increased incidence of the disease in the United States.

At least one State, California, has enacted legislation to facilitate development of an AIDS vaccine. Last fall, California passed a law, assembly bill 4250, which addresses each of the obstacles the Institute of Medicine said would stymie vaccine development.

The California legislation is a laudable first step. Federal legislation should go further in the area of tort reform. It should ensure that judges and juries do not have the power to second-guess the judgment of FDA experts who, after spending years evaluating the benefit/risk ratio of a vaccine, will have concluded that the benefit to the public from an HIV vaccine outweighs the unavoidable risk inherent in such a vaccine. Federal law should clearly protect the manufacturers of an AIDS vaccine from liability without fault.

For these reasons, we support the following Congressional actions: number one, increased funding for programs directed toward serotyping; number two, establishment of a central repository of AIDS virus isolates and patient sera; number three, tort reform to establish fault-based products liability, including a victims compensation fund to discharge society's responsibility to pay for the larger benefit of a population protected against the deadly HIV; number four, making a vaccine against HIV a compulsory vaccine for the general population.

We urge that these steps be taken now when the biotechnology companies developing HIV vaccines are on the verge of making the decision of whether or not to mount the very expensive scale-up and pre-clinical development programs necessary before the commercialization of their R and D efforts.

Thank you.

[The prepared statement of Dr. Martin follows:]

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BEFORE THE

COMMITTEE ON LABOR AND HUMAN RESOURCES

UNITED STATES SENATE

STATEMENT OF

DAVID W. MARTIN, JR., M.D.

VICE PRESIDENT - RESEARCH

TO URGE

LEGISLATION TO FACILITATE THE

DEVELOPMENT OF AN AIDS VACCINE

January 15, 1987

STATEMENT OF DAVID W. MARTIN, JR., M.D.

Mr. Chairman, and members of the committee, Genentech is a leading biotechnology company committed to the research, development and commercialization of pharmaceutical products made through recombinant DNA techniques. Genentech is one of the biotechnology companies actually pursuing development of an AIDS vaccine. I appreciate the opportunity to share with you the promise, and the frustrations, of our efforts in this area.

Today mankind is confronted with potentially the most insidious disease ever known -- one which attacks the immune system and renders it incapable of resisting the invading virus. Those who develop the symptoms of it will die.

Acquired Immune Deficiency Syndrome -- AIDS-- is primarily a sexually transmitted disease with no early warning signs. After infection with Human Immunodeficiency Virus (HIV), individuals may be healthy for five or more years during which time their serum may not even test positive for AIDS antibodies. These individuals, unaware of the infection, unwittingly spread it. Health officials suggest only 25% to 50% of those infected will develop the symptoms; the rest remain carriers of the dread disease.

Between 1981 when the disease was first diagnosed and the end of 1986, over 27,000 people in the United State have been reported to have AIDS. By the end of 1986, over 15,000 had died. The U.S. Public Health Service estimates that by 1991 there will be 270,000 reported cases of AIDS. Considering estimates that one to two million people may already be infected, the Public Health Service's estimate of AIDS cases in 1991 seems extraordinarily conservative.

The costs to society of this dread disease are staggering. The human costs -- the emaciation, the dementia, the pain, the suffering, the loss of productivity, the loss of young lives -- are incalculable.

The dollar costs are astronomical. The National Academy of Sciences recently reported that the average hospital costs alone range from $50,000 to $150,000 for each AIDS patient. The Public Health Service projects that direct costs of care for AIDS patients in 1991 alone will be $8 billion to $16 billion. It is little wonder that eradication of AIDS is America's highest health priority.

What can be done and how can we wage war on this disease?

Diagnostic tests are now available which are capable of detecting antibodies to the AIDS virus. These diagnostics have done much to enhance the safety of the Nation's blood supply. Appropriate criteria are in place for identifying and excluding blood and plasma of donors who are at increased risk of transmitting the disease.

Unfortunately, AIDS cannot be cured at this time. One drug, AZT, has shown promise in inhibiting a key enzyme, reverse transcriptase, involved in the replication of the virus. On balance, however, the extensive efforts directed toward screening and testing antiviral products, products to rebuild the immune response and products to treat opportunistic infections associated with AIDS have not been successful. While we must continue the search for effective treatments, even an effective treatment is not a complete answer.

A major hope in the struggle against AIDS is that development of a vaccine will be possible. The consensus of experts including those at the World Health Organization and the National Academy of Sciences is that, even if the scientific and nonscientific issues which cloud the development of an AIDS vaccine can be resolved, a vaccine is five or more years away. Although a vaccine is years away, this should not detract from the tremendous strides the scientific community has taken in understanding HIV and how it works, nor should it dash hopes for a vaccine.

Immunization against AIDS and prevention of it in our population and in the world at large must be our goal. Historically, immunization has been one of medicine's most spectacularly successful and cost effective preventive health measures. One reason has been because government or other organizations were willing to step forward at the appropriate time with particularly powerful resources. Through immunization in our lifetime we have seen the global eradication of smallpox. We have also witnessed the virtual elimination in the United States of poliomyelitis and have drastically reduced measles, mumps and rubella. There are now thousands of children alive and well who would have died of these diseases if our modern vaccines had not been developed. Such is the hope of vaccines.

Vaccines all work on the same basic principle by getting the body to make antibodies which will recognize and bind to an infectious agent, signaling other parts of the immune system to kill or inactivate the agent. Perhaps the major scientific obstacle involved in producing an effective AIDS vaccine is the virus variation problem.

This problem stems from the fact that there exist multiple strains of HIV with immunologically distinct surfaces. This enables the virus to evade an immune response, because the immune response which eliminates one type of virus may be less effective or ineffective in eliminating a virus with a different spectrum of surface component. Practically speaking, an individual vaccinated with the components of one type of virus might be able to mount an immune response against the homologous virus, but not necessarily against a different strain of virus.

A similar situation exists in the case of polio where there are three immunologically distinct forms of the virus. All three types of virus are included in a polyvalent vaccine. This vaccine has been spectacularly effective, and it is obvious that a similar polyvalent vaccine for AIDS might protect individuals against the various types of the virus.

Unfortunately, the number of HIV types is completely unknown at this time. Thus, are there only a few types of HIV, as is the case with polio? Or, are there an enormous number of types, as is the case with the influenza virus? These questions are central to the development of an AIDS vaccine. A large number of virus types (>50) might make the practical production of an AIDS vaccine virtually impossible.

Federal efforts should support and expedite ongoing research efforts. First, the Congress should provide increased funding to greatly enhance and fully support the NIH and any other governmental or private sector efforts to conduct serotyping of the AIDS virus. The same typing program which was done for polio is essential for the development of an AIDS vaccine. The technology for this typing currently exists. The result of this typing will allow the various investigators working on an AIDS vaccine to choose the genes from the appropriate viral isolates for inclusion in a polyvalent vaccine in order to provide broad protection against the different types of AIDS virus.

Second, we urge this committee to take steps to develop a central repository for viral isolates and patient serum, so that they are readily and easily available to all qualified scientists. Third, we ask for greater coordination of federal efforts in order to make more readily available information concerning governmental research projects and the data resulting from such projects.

The powerful tools of biotechnology have much to offer in the development of vaccines, particularly in connection with an AIDS vaccine. Genetically engineered vaccines, based on portions of the recombinantly produced surface of the AIDS viral envelope, are inherently much safer than conventional vaccines which use weakened or killed viruses. The recombinantly produced fragment merely mimics the portion of the virus in order to trigger an immune response. Absolutely no one will develop an AIDS infection from this type of vaccine. No vaccine, however, is 100% safe. Moreover, it will not be until after the widespread use of an AIDS vaccine that all the infrequent, adverse effects are even identified.

Testing of an AIDS vaccine has its own unique problems. There are no good animal models. Even though the HIV infects certain non-human primates, it does not give them AIDS. Consequently, animal tests can only determine if the vaccine prevented the viral infection by testing for antibodies to the HIV and for the HIV per se. Such tests cannot predict for certain whether the vaccine will prevent AIDS in humans. Only direct tests on humans, which raise many social, ethical and political questions, will be able to determine whether the vaccine is effective. Because of the long latency period of HIV in humans after infection, it may take several years to determine whether it effectively prevents AIDS.

In March of 1986, this Committee and the House Committee on Energy and Commerce asked the National Academy of Sciences, Institute of Medicine (IOM) to help formulate a new vaccine policy. IOM convened a conference of 70 leading experts on vaccines and immunization. The discussion at the conference focused on the continuing inadequacy of government and industrial investment despite the cost-effectiveness of immunization. The IOM conference found that promising research results are not developed into products because of (1) the enormous expense of clinical trials; (2) the unknown market size, particularly with adult vaccines which unlike childhood vaccines are not mandated by the states; and (3) the potential for large and unpredictable awards in products liability cases where the manufacturer has properly made a vaccine which has an inherent and known risk; one which cannot be avoided.

The National Institute of Medicine made the same points in its recently published, comprehensive analysis of the AIDS epidemic:

> Much of the expertise in vaccine development is in the industrial sector. However, contributions of industry to the development of an HIV vaccine are inhibited by the substantial developmental costs in the absence of a significant probability of financial return and by apprehension over potential liability incurred in the course of vaccine distribution. Creative options for the governmental support of industrial research, guarantees of vaccine purchase, and the assumption of reasonable liability should, therefore, be actively explored and encouraged.

See Confronting AIDS: Directions for Public Health, Health care and Research (1986), at 27.

In its report, the IOM later aptly observed:

> Another difficulty involves the unwillingness of many pharmaceutical companies to commit to a significant financial and scientific investment in vaccine development in the face of present liability threats and insurance considerations. Concerns exist over liability both during the testing phase of vaccine development and after a vaccine is licensed but are perhaps greater during the latter period. Unless problems of vaccine liability are dealt with swiftly and effectively, no manufacturer may be willing to produce HIV vaccine for use in the American market.

Ibid, at 229.

The Institute of Medicine has correctly

identified the barriers to development of vaccines. The liability questions loom particularly large.

These are troubling questions. Does the manufacturer who properly prepared and labelled the vaccine or the equally innocent victim who is injured by the infrequent, but unavoidable, side effect bear the loss? If the side effect was unknown, should the manufacturer or the innocent victim have to bear the loss?

Under well-established law, the vaccine manufacturer is not liable for injuries when the vaccine has been properly manufactured and adequate warnings of known risks have been provided. Some courts have acted contrary to these principles and forced manufacturers to pay sizable damage awards including awards of punitive damages. In the first significant case, Reyes v Wyeth Laboratories, 498 F.2d 1264 (5th Cir. 1974), the Court suggested compensation should be provided to the innocent victim and that the cost is best borne by the manufacturer.

The clear signal to vaccine manufacturers from the Reyes decision, and those which follow in its wake, is that liability may be found without fault. Subsequent case rulings have further encouraged the filing of law suits departing from liability associated with fault. *See* Kitch, E.W. "The Vaccine Dilemma," Issues in Science and Technology (Winter 1986), at 108 - 121. These decisions have the effect of unjustifiably making the manufacturer the insurer.

The uncertain legal environment has had tangible adverse effects on vaccine manufacturers: It has discouraged the manufacture and innovation of vaccines. Some pharmaceutical manufacturers have chosen to opt out of the vaccine business altogether.

The remaining manufacturers have been forced to reflect the increased costs in their prices. Last fall, when Congress considered the childhood vaccines bill, the number of manufacturers had dwindled to one manufacturer of polio vaccine, one manufacturer of vaccine for measles, mumps and rubella and two DPT vaccine manufacturers. In May, 1986, the two manufacturers of DPT vaccine announced tremendous price hikes to cover the cost of law suits. One of the manufacturers, which had priced a dose of vaccine in 1982 at $.11, was reportedly charging $11.40 per dose after June, 1986, to cover the cost of litigation through self-insurance.

The same disincentives for manufacturing childhood vaccines exist for developing an AIDS vaccine. In addition, there are other obstacles to the development of an AIDS vaccine. Unlike the childhood vaccines whose widespread use has identified adverse side effects, we cannot accurately know or guess what side effects will be associated with an AIDS vaccine. Unlike the childhood vaccines which the states make mandatory for each child, we do not yet know whether or when the government will make an AIDS vaccine mandatory.

The question of who will use such a vaccine is a critical one to answer for purposes of commercialization. It has even more significant health consequences. From a public health viewpoint, an HIV vaccine should be a universal vaccine. There are a number of reasons why the government should make an AIDS vaccine, once developed, compulsory.

The most important consideration is that the current epidemiology of AIDS in the United States and its prevalence in the identified high risk groups such as homosexual men and IV drug users most likely reflects transmission of the virus five or more years ago. In five years, we may well see an entirely different epidemiologic picture for HIV infection with a much greater prevalence in the general heterosexual population. Indeed, we already know from the epidemiology of HIV infection in Africa that at least certain HIV strains can be spread through the heterosexual population. For this reason, vaccination of the general population at the earliest possible date is essential to prevent anything remotely similar to the widespread heterosexual epidemic now in progress in several African nations.

There is absolutely no way to guarantee with 100% certainty that the nation's blood supply will remain entirely safe with respect to HIV transmission. Small but finite risks exist at the present time that individuals who have the HIV infection, but who have not yet developed the antibodies to HIV which the diagnostic tests can detect, will on occasion donate blood and contaminate the nation's blood supply. Generalized vaccination of the heterosexual population is the only way to reduce the risk that contaminated blood is not inadvertently administered to unprotected individuals.

We cannot afford to allow HIV to become endemic in the way that hepatitis B has. Currently, there are over 2 million carriers of hepatitis B in the United States and nearly 200 million in the People's Republic of China. As has happened for hepatitis B, once a significant number of women of childbearing age are infected with HIV, the infection may become endemic because it is frequently passed to the children of such mothers. If we do not intervene now to reduce the number of HIV seropositive women of childbearing age, we may be faced in the future with a widespread chronic endemic infection in a large pool of carriers.

The most successful vaccination programs in the United States have both involved the vaccines which were administered universally to the general population. Generalized vaccination programs were responsible for the success of the smallpox and polio immunization programs. Vaccines targeted at high risk groups without compulsion, such as hepatitis B vaccine, have failed to prevent an increased incidence of disease in the United States.

At least one state, California, has enacted legislation to facilitate development of an AIDS vaccine. Last fall California passed a law, Assembly Bill No. 4250, which addresses each of the obstacles IOM said would stymie vaccine development. California's law provides for compensation to the innocent victims whose injuries are caused by an AIDS vaccine; it provides some needed tort reform to assure only manufacturers at fault are liable; it guarantees the purchase of a certain number of doses of any FDA approved AIDS vaccine; and it provided $6 million for clinical trials.

The California legislation is a laudable first step. Federal legislation should go further in the area of tort reform. It should insure that judges and juries do not have the power to second guess the judgment of FDA's experts who, after spending years evaluating the benefit/risk ratio of a vaccine, will have concluded that the benefit to the public from an HIV vaccine outweighs the unavoidable risks inherent in such a vaccine. Federal law should clearly protect the manufacturers of an AIDS vaccine from liability without fault.

Immunization is a social good. Mass immunization can create "herd immunity." In the case of smallpox, universal immunization ultimately resulted in eradication of the disease. Thus, society benefits when its people are immunized and society should bear the costs when innocent victims develop known adverse reactions from vaccines of which manufacturers have warned, but which they have no power to eliminate. For similar reasons, society should bear the cost when innocent victims develop previously unknown adverse reactions from vaccines. In the case of an AIDS vaccine, the costs of a victim compensation program with reasonable limits for innocent victims is a small price to pay compared to the spiraling costs for hospitalization and treatment of AIDS patients which could be $16 billion and climbing yearly by 1991.

For these reasons, we support the following Congressional actions:

1. Increased funding for programs directed to serotyping;
2. Establishment of a central repository of HIV isolates and patient sera;
3. Tort reform to establish fault-based products liability, including a victim compensation fund to discharge society's responsibility to pay for the larger benefit of a population protected against the deadly HIV;
4. Making a vaccine against HIV a universal vaccine.

We urge that these steps be taken now before the biotechnology companies developing HIV vaccines have to face the decision of whether they will commercialize their inventions or not.

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The CHAIRMAN. You have given us a lot to think about in that testimony, both the ethical issues as well as the viability issues, commercial matters, which we will come back to.

Dr. Katz, we welcome you, a distinguished pediatrician. We are delighted to have you here today.

Dr. KATZ. Thank you, Mr. Kennedy, Mr. Weicker, Mr. Metzenbaum, Mr. Adams. This is a special opportunity for me to speak with you about some selected issues which we face in the development and the use of vaccines to prevent AIDS.

My own interest in vaccines spans 30 years of involvement with basic virologic research, clinical investigation, vaccine trials, research consultation and, more recently, public policy.

Currently, I serve as chairman of the Immunization Practices Advisory Committee of the United States Public Health Service, which formulates the recommendations for use of vaccines in this country.

Additionally, Dr. Fauci has asked me to be a consultant to the AIDS Executive Committee of the National Institutes of Health. For several years, from 1982 to 1985, I served on several Institute of Medicine committees which at the request of the National Institute of Allergy and Infectious Diseases examined priorities in vaccine development and the very interaction to which Dr. Martin spoke of the public and private sectors in vaccine innovation.

I think it is important to review briefly the past history of vaccine development in this country in order to look at the current challenge with some perspective. During the past 35 years, we have been eminently successful in developing safe and effective vaccines to prevent a multitude of virus infections, including influenza, poliomyelitis, measles, mumps, congenital rubella, and hepatitis B.

These successes have all represented combined endeavors of individual scientists and groups of researchers in various settings, university medical centers, research institutes, governmental agencies, including NIH, the Centers for Disease Control, the Department of Defense, and the Food and Drug Administration, and private industry.

The interplay among these individuals and groups has been dynamic, healthily competitive, and in many instances positive and collaborative. Most of those who attended a July NIH workshop on AIDS vaccine sponsored by the National Institute of Allergy and Infectious Diseases left those sessions with guarded optimism, but renewed determination to seek effective vaccines for the prevention of HIV infections.

It was apparent that much information remained to be acquired regarding many aspects of AIDS. During my earlier statement, I spoke with optimism, but I think it is important to underline what Dr. Fauci has already mentioned, and that is we have no previous experience with the prevention of human infections due to this particular class of agents, the retroviruses. All the other successes which we mentioned are with different types of viruses.

In thinking of the directions in which vaccine development should go, it is my best judgment that the most important intervention will be in the prevention of the original infection with human immuno-deficiency virus, not in the prevention of disease in those important, unfortunate individuals who are already infected.

Their salvage will be better addressed by chemotherapy, immunotherapy and combinations of both.

Even if induced animal infections such as those mentioned in chimpanzees and other non-human primates can serve as models of human infection, it is important to appreciate that retroviruses may behave very variably in different species, so that the requisite transition from laboratory and animal experiment to human study will be critical and frought with anxiety.

The eventual strategies for intervention with vaccines to prevent human infection will be conclusively determined only by studies in man. Thus, there are ethical, legal and social issues to be considered in parallel with the very complex scientific ones.

There are major concerns regarding liability. Dr. Martin has spoken to these. This is an area where government intervention is critical to the encouragement of successful clinical studies.

The recently-enacted National Childhood Vaccine Injury Act of 1986, Public Law 99-660, could well serve as a prototype for federal and/or State development of legislation to establish an equitable, reasoned approach to compensation and liability for alleged vaccine-related injury.

This issue is considered at great length in several recent reports from the Institute of Medicine. To encourage the pharmaceutical industry to develop and to distribute potential AIDS vaccines, the system must be corrected in a way that will remove the current legal interpretation of strict product liability while still protecting vaccine recipients and guaranteeing compensation for any injuries incurred.

The planning and implementation of the initial human clinical trials will merit careful scrutiny by an expert advisory group. Such trials will have to be conducted in special settings, such as those which Dr. Fauci described in the vaccine centers.

When a vaccine is shown to be successful in generating an immune response, the next steps will be even more difficult. How does one select a group of susceptible individuals at risk in order to assess the efficacy of such a vaccine?

There will be many issues to be considered, including the aforementioned confidentiality, compliance with long-term follow-up, and the anticipated cost of such studies. Once an apparently successful vaccine has been developed and brought through phases I and II, the question arises again as to at what age and to whom would one administer this vaccine.

It will be exceedingly difficult, if not impossible, to identify in advance those individuals whose eventual choice of lifestyle may make them at greater risk of AIDS or who will be subjected to environmental factors that may put them at higher risk.

The question will arise whether this is a vaccine which should be administered to all children, and Dr. Martin has raised that question, early in life, as is now our accepted practice for the common, preventable diseases, diptheria, whooping cough, tetanus, polio, measles, mumps, rubella.

The social stigma of AIDS may arouse significant reluctance of parents to have their children immunized against a disease which they cannot envision ever affecting them.

However, an ideal age might be age 10 or 11 years, prior to or at the onset of observed sexual activity in our society.

The issues of funding are obvious; they have been spoken to and I will not reiterate them.

In summary, I believe that the priorities which one can assign to the development of an AIDS vaccine are unequaled by any other disease which we face today or have faced in recent years, so that in the consideration of all of these issues we can only adopt a positive approach to the development of a safe and effective vaccine and the mobilization of funds to continue and foster the research and development leading to it.

Thank you, Mr. Chairman.

[The prepared statement of Dr. Katz follows:]

STATEMENT BY SAMUEL L. KATZ, M.D.

PROFESSOR AND CHAIRMAN, DEPARTMENT OF PEDIATRICS

DUKE UNIVERSITY SCHOOL OF MEDICINE

TO THE SENATE LABOR AND HUMAN RESOURCES COMMITTEE

THURSDAY, 15 JANUARY 1987

Mr. Chairman and Committee members,

This is a welcome and privileged opportunity to speak with you today about some of the issues which we shall face in the development and use of vaccines to prevent Acquired Immune Deficiency Syndrome (AIDS). My own interest in vaccines spans 30 years of personal involvement beginning with basic virologic research, extending into clinical investigation and vaccine trials, merging into research consultation and, more recently, public policy. Currently I am Chairman of the Immunization Practices Advisory Committee of the United States Public Health Service (at the Centers for Disease Control) and a consultant to the AIDS Executive Committee of the National Institutes of Health. From 1982 until 1985, I was Chairman of a committee of the Institute of Medicine of the National Academy of Sciences to study at the request of the National Institute of Allergy and Infectious Diseases the establishment of priorities for the development of new vaccines. Simultaneously I was a member of a second committee at the Institute of Medicine investigating public-private sector relations in vaccine supply and innovation. These experiences leave me with an overall optimism regarding the ability of our nation to mount eventually a successful vaccine program to prevent AIDS.

The past history of vaccine development in this country is important to review briefly in order to examine the current challenge with some perspective. In the past 35 years we have been successful in developing safe and effective vaccines to prevent a multitude of virus diseases including influenza, poliomyelitis, measles, mumps, rubella, and hepatitis B. These successes represent the combined endeavors of individual scientists and groups of researchers in varied settings including university medical centers, research institutes, governmental agencies (including the National Institutes of Health, the Centers for Disease Control, the Department of Defense and the Food and Drug Administration) and private industry, especially the pharmaceutical field. The interplay among these individuals and groups has been a dynamic, healthily competitive one and in many instances a positive and collaborative relationship. Previous witnesses before your committee this morning have already attested to the unique attributes of AIDS, the virus (HIV) which is responsible for it, the immune response to the infection and the problems in research and health education. With the mobilization of talented scientists in the many environments to which I have referred above, there are already significant advances occurring in a dynamic fashion increasing our understanding of the virus, the immune response to infection and those characteristics of both aspects which must be taken into consideration in research and development of a preventive vaccine. The dynamic kaleidoscope of AIDS research is such that almost daily new information is acquired regarding HIV and its interactions with the human host.

On July 28th and 29th of 1986 I was privileged to serve as Chairman of a two day workshop organized by the National Institute of Allergy and Infectious Diseases to examine issues in the development of vaccines to prevent AIDS. Most impressive was the enthusiasm and optimism of the many investigators who attended and shared research results. Again, they represented every facet of the public and private biomedical scientific establishment. Most of those in attendance left the sessions with guarded optimism and a renewed determination to seek effective vaccines for the prevention of HIV infections and their dread consequences. It was apparent that much information remains to be acquired regarding many aspects of AIDS, ranging from its pathogenesis through the natural history, the epidemiology, the relationship to other infectious agents, the immune response and the availabilty of relevant animal models. Despite my earlier statement regarding our success with many other viruses in the past, it is important to emphasize that we have no previous experience with the prevention of human infection due to this class of agents, the retroviruses.

In thinking of the directions for vaccine development, my judgment is that the most important intervention will be in the prevention of original infection, but not in the prevention of disease in those unfortunate individuals already infected. The latter aspects will be better addressed by chemotherapy, immunotherapy, and possibly combinations of both.

Even if induced animal infections such as those of chimpanzees can serve as models of human infection and their prevention by investigative vaccines, it is important to appreciate that retroviruses may behave quite variably in different species so that the eventual transition from laboratory to human study will be fraught with anxiety. The eventual vaccine strategies for prevention of human infection will be conclusively determined only by studies in man. This raises major concerns regarding liability in the conduct of these studies. This is an area where governmental intervention will be critical to the encouragement of legitimate, thoughtfully planned clinical studies. The planning and implementation of initial human clinical trials will merit the scrutiny of expert advisory groups. Such trials will need to be conducted in special settings for initial observation but then include the facilities for long-term surveillance, both for safety and efficacy. If/when a putative vaccine is shown to be successful in the generation of an immune response, the next steps will be even more difficult. How does one select a group of susceptible individuals at risk in order to assess the efficacy of such a vaccine in prevention of HIV infection? Among many considerations will be surveillance, maintenance of confidentiality, compliance with clinical followup, and anticipated duration of observations. Even if/when an apparently successful vaccine has been developed, a more sensitive question will be the selection of what population, and at what age, to administer the vaccine. It would be exceedingly difficult, if not impossible, to identify in advance those individuals whose choice of lifestyle or other environmental factors will put them at high risk. The question will arise whether this is a vaccine which should be administered to all infants, early in life, as is accepted practice now for the common preventable diseases of infancy and childhood (diphtheria, whooping cough, tetanus, poliomyelitis, measles, mumps and rubella). The social stigma of AIDS may arouse significant reluctance of parents to have their children immunized against a disease which they cannot envision ever affecting them.

The mobilization of funds to support the lengthy and multiple research efforts which will lead to the development of successful AIDS vaccines will again be a collaborative one involving both the government and the private sector. Similarly the educational programs which will be necessary in order to facilitate vaccine studies and eventual vaccine utilization will require skilled materials and performance by educators and health professionals. The necessary funding has already been estimated by the Institute of Medicine group chaired by Drs. Sheldon Wolff and David Baltimore. These must be allocated as new funds, not taken from other essential programs the success of which may well hold unexpected clues to our understanding of AIDS and human immunodeficiency virus. Inappropriate reallocation of funds originally intended for other research would be counterproductive and deleterious to research in multiple other areas of major human health significance.

The recently enacted "National Childhood Vaccine Injury Act of 1986" (Public Law 99-660) may well serve as a prototype for Federal development of a program to establish a fair, constant approach to compensation and liability for alleged vaccine-related injury. This issue is considered at great length in the report of the Institute of Medicine Study on Vaccine Supply and Innovation (National Academy Press, Library of Congress Catalog Card #85-60772). To encourage the pharmaceutical industry to develop and distribute potential AIDS vaccines, the system must be corrected in a way that will remove the current legal interpretation of strict product liability while still protecting the vaccine recipient and guaranteeing compensation for any injury incurred.

There can be no doubt that a vaccine to prevent infection with human immunodeficiency virus receives the highest priority for development. In considering those factors which bear on the establishment of such priorities, all of the following items are relevant.

Current research progress relating to the agent

Morbidity and mortality of the infection and the disease

Identification of target population

Technical feasibility and the probability of success

The cost of development and production

Predicted efficacy of the vaccine

Delivery of the vaccine (the route and the number of doses)

Adverse reactions encountered

The cost per dose and course of immunization

The duration of protection afforded

Acceptance by health personnel and by the intended target population

In considering vaccines for AIDS, nearly all of these issues can be viewed in a very positive fashion with the anticipation that the known morbidity and mortality of the disease will ensure acceptance of a safe and effective vaccine as well as the mobilization of funds to foster the development.

The **Chairman**. Thank you very much.

I think here in our panel we have individuals who are about as up to speed as anyone in the country or any individuals in terms of what is happening out in the research area, certainly from within the governmental research programs, the national institutes, and I think David Martin in terms of what is happening out in the private sector. So I am looking forward to having the chance to get your responses to some of the questions that I have.

I think Dr. Fauci had indicated earlier that you do believe that some form of AIDS vaccine may be available for testing sometime at the end of this year or by the early part of next, is that right?

Dr. **Fauci**. Yes, sir.

The **Chairman**. One of the issues which must be resolved before a vaccine can be tested is whether its efficacy will be tested in primates first or directly in humans. I would like to ask you, Dr. Fauci, and the whole panel, what your opinion about this question would be, given the sense of urgency about the development of a vaccine, the delay that comes in the testing of the primates, but given the other kinds of ethical issues which would be faced by testing in individuals first.

What is your opinion about whether it is going to be essential to test it in primates or humans first?

Dr. **Fauci**. You mentioned the term efficacy, Mr. Chairman, and I think that is really the critical word there. There is no question that any material that will be put into man should be tested first for safety, toxicity, and immunogenicity in animals.

The standard approach would be to get an animal model that most closely resembles the human. In this situation it is the chimpanzee that can be infected with the human virus.

The standard approach taken by most investigators is to show that immunization with a candidate vaccine will prevent the infection in an animal that is able to be infected and then go on to humans.

The difficulty with the chimp model is that this animal does not get the disease. The chimp gets infected, but it does not get immuno-suppressed and does not get the disease. So it could be argued by some that even though you inject a vaccine into the chimp and either show efficacy or not show efficacy, this may not be directly extrapolated to man.

So it is an arguable point. It is not an open and shut case.

The **Chairman**. Dr. Katz?

Dr. **Katz**. I would support Dr. Fauci's presentation. It must be tested in animals first, but that is not going to give all the answers because we do not have a perfect animal model.

With polio, you could produce polio, paralytic disease in monkeys. With measles, you could produce measles in monkeys. The next step really was rubella, where what we were trying to prevent was the infection of a fetus in utero.

We were never able to develop an animal model of human rubella infection. We went through the monkey model because there were a number of questions that could be answered, such as Dr. Fauci has mentioned, safety and immunogenicity. But we never knew until we got to man and continued with trials that it would prevent the infection of a baby in utero.

So there will be, again, unanswered questions with HIV vaccines, but there are still essential steps in the testing in primates that I think have to precede human trials.

The **Chairman**. You included this testing when you talked about the time that would elapse before we might have at least some results in terms of a vaccine that would be safe and efficacious and that would be approved when you gave us that five to eight years?

Dr. **Fauci**. Yes, that is including the initial testing for safety and immunogenicity in animals, sir.

The **Chairman**. And would you agree that even vaccines that have been tested in primates and then in human beings in a few instances ended up having unprecedented and undesirable effects? Is there a danger of this kind of an outcome with a new AIDS vaccine?

Dr. **Fauci**. There is no question that testing in animals can give you a good sense of the types of toxicities you may see, but it certainly will never give you an absolute, complete answer.

We generally find out about the very rare toxic effects of a particular product after it has been administered to large numbers of people. Sometimes you see problems early on with smaller numbers. This is one of the major rationales for going gradually from a phase I to a phase II to a phase III.

Hopefully, you will pick up the majority of the deleterious effects in phase I studies which are geared toward safety and immunogenicity, but it is also conceivable that you will not see certain of them until the vaccine is widely used in phase III studies and thereafter.

The **Chairman**. Dr. Martin, I want you to respond to these, too. Perhaps you would respond to the first question.

Dr. **Martin**. My response, I think, would be a little bit different. I would say that given that the safety was shown in a chimp model, for instance—in fact, safety can be determined in other non-human primates than the chimp—then obviously an efficacy study would need to be done in chimps.

Given that it is safe and non-toxic in chimps, I think a positive result—i.e., some evidence of protection of infection by HIV in a chimp—would be very encouraging. On the other hand, I do not think that lack of protection in a chimp from HIV infection should be unnecessarily discouraging, the reason being that chimps and humans have the potential of responding somewhat differently to different immunogens. Their immune systems, while very similar, are not identical. Thus, lack of proven efficacy in a chimpanzee model should not deter the study, at least phase I, in a human population.

The **Chairman**. For the purposes of the discussion, the animals we are talking about are primates; specifically, chimps. Is that correct?

Dr. **Martin**. Yes, sir.

The **Chairman**. We all agree with that.

Are there sufficient numbers of chimps around?

Dr. **Martin**. I would categorically say no, there probably are not at the moment sufficient numbers of well-cared-for, studied chimps available. I know Dr. Fauci has been very much involved in trying to acquire such animals. That is, I believe, going to be a significant problem.

The **Chairman**. Dr. Fauci, is your response to the earlier question about efficacy studies related to chimps or to other primates?

Dr. **Fauci**. The only animal model in which you can determine efficacy is the chimp and then only in regard to infection, not disease. This is because the chimpanzee is the only animal that can be infected with the human virus. So I actually was referring to the chimp there.

And I agree with what Dr. Martin was saying that if you do not show efficacy in this animal, that does not necessarily deter you from going into humans.

The **Chairman**. Could we talk a little bit about the problems that we might face that would prevent a vaccine from going to the market area once it has been tested? What are they?

Dr. **Martin**. Well, I think they fall into three areas. The first is the lack of product liability protection for the manufacturer or distributor. The second is the enormous cost——

The **Chairman**. I know the enormous problem we faced in that with childhood diseases. Our Committee wrestled with that for 15 years. We are talking about a handful of cases that spin off from the use of the live vaccines in polio in predictable number.

The failure to come to grips with it almost drove that company right out of production, so this is an enormously important question. We finally came up with a solution to this in the last year, but it arouses enormous kinds of differences here in this body.

So when we talk about eliminating product liability, that is a major kind of a question as well that involves, even if they produce these, whether they are going to produce them safely and effectively or whether there is not going to be negligence even in the production of them and whether you free companies from putting things out which may be an approved vaccine but not done in the way that it should be.

So we do not want to unduly alarm people, but we do not also want to have sort of a magic wand that if you eliminate the product liability, we are resolving the problem. That is obviously an issue that we have to worry about.

What are the others?

Dr. **Martin**. The others have to do with the enormous cost of the pre-clinical and clinical development. Perhaps you are aware that in a research and development program, for instance, for an AIDS vaccine that the successful research effort really accounts for only about ten percent of the costs of developing an AIDS vaccine.

The third is the current market climate; that is, what is going to be the market size. We do not know what the market size is, and therefore when it comes to managing essentially a small-venture company such as Genentech, we always have to concern ourselves with whether we are betting the company on what is, in effect, a very risky project.

The **Chairman**. Any other comments?

Dr. **Katz**. Yes, I would like to add one comment to your remarks, Senator Kennedy, and that is relating to whether a company could come to the market with a sloppily-prepared or unsafe vaccine.

I think the other agency, the Food and Drug Administration, through which any vaccine must be passed and tested carefully prior to licensure, is our best safeguard against that.

I think that that agency is staffed with scientists who are very familiar with vaccine development, and all of the studies that we are talking about now include deliberations and collaboration with scientists in all the agencies, not just the National Institutes of Health.

The CHAIRMAN. Doctor, you are the professional on it. When you use live vaccines, you get a certain number of predictable cases of polio.

Dr. KATZ. That is correct.

The CHAIRMAN. Those people bring the cases and they go to juries and they see a malformed child out there, and they brought those cases and that is predictable. They can produce under the best of circumstances—it is predictable that some children will be injured.

Those findings against that company raised the price, as we heard earlier, from 11 cents to $11 dollars.

It just about drove that company out of the production of it, and it is not that they are producing an inferior product and it is not that they have not got FDA approval.

We have just been wrestling with this problem for a long time and it is certainly a problem that we will have to solve with this vaccine as well.

We are going to have to be creative and imaginative and work with the scientists and the private sector to be able to do it.

Dr. MARTIN. Mr. Cunningham, I think, has a comment.

The CHAIRMAN. Mr. Cunningham?

Mr. CUNNINGHAM. I would just like to add these remarks about it. In the California model of tort reform, a couple of points were the guiding points in development of that legislation.

One was that the sponsors of that legislation were not asking for the manufacturer to be excluded or to excuse from fault, responsibility for his fault. For instance, there was no change in the law as it relates to the negligent manufacturer of a drug. If you do not follow the recipe, you have liability.

The CHAIRMAN. Yes.

Mr. CUNNINGHAM. The two areas that were addressed were, one, the design of the vaccine and the warning of known risks or known side effects, and in that case the California Legislature basically established that if the manufacturer had not been negligent in designing the vaccine or in warning of the known risks, that would be the area where strict product liability would not be applied. It would be liability based on fault.

And then the other principle that the California Legislature followed was that this is a societal problem and the costs of, again, predictable side effects—you do not know what they will be, but it is predictable that there will be side effects—should not be borne either by the victim or by one or two companies who have undertaken to produce the vaccine.

Therefore, they sought to establish a victims compensation fund.

The CHAIRMAN. Well, I do not want to get into this more than we already are, but you had a person that was getting the polio vaccine; a mother goes in and the possibility of contracting the disease may be one in 600,000. Now, that is notice.

Dr. KATZ. One in three million.

The **Chairman**. One in three million, so the mother is going to go on in there and get the vaccine. There are going to be other children who do not get the vaccines. The child who gets the vaccine, through the effect of the live vaccine, effectively immunizes the other children.

Now, the child gets polio. Now, are you going to say, well, you were warned? You had one chance in three million and you were warned? I mean, I do not want to get back into that debate here today, but it does not lend itself to a very quick, seat-of-the-pants response.

It is a tough one and it is one we are going to have to address, and I think we ought to be able to address it. I do not hesitate in saying we have to address it; we will. You know, when we are talking about all the progress that we are going to do and all these matters, there are some very important ethical issues and questions.

Let me ask Dr. Fauci, say we get a vaccine. Do you think we are talking about a compulsory immunization program in this country?

Dr. **Fauci**. The policy for vaccine usage is one that is established by the Public Health Service through a variety of consultative mechanisms. Dr. Katz just mentioned he is the chairman now of the Vaccination and Immunization Advisory Committee.

And that is a question that I really cannot answer right now. It really will depend on bringing the best individuals from various segments of society and approaching that very important question.

The **Chairman**. Where do you come out on it now?

Dr. **Fauci**. As a scientist and not as a policymaker, I would say that, given the fact that we know that this virus can be spread heterosexually and that it is a sexually transmitted disease, I would lean in favor of more extensive immunization, as opposed to restricted.

The **Chairman**. Dr. Katz?

Dr. **Katz**. I think we are loathe in this country to mandate that you must do things of this sort.

The **Chairman**. We are.

Dr. **Katz**. And if this were to be a vaccine used in——

The **Chairman**. Well, we do it tentatively with regard to the children's diseases in order to be able to go to school.

Dr. **Katz**. But you can get excused.

The **Chairman**. You can, that is true.

Dr. **Katz**. You can get a letter from your physician that says your mother does not believe in this.

The **Chairman**. That is right, but those are the exceptions.

Dr. **Katz**. Those are the exceptions, but I think that there are several issues involved here, and one is the one you have mentioned. If this were a vaccine that is given to children, by and large the preventive medicine practices in public health clinics and in private practice in this country are such that childhood immunization is widely followed.

More than 98 percent of children have the recommended vaccines even before they get to school, so that there is the custom and the tradition and the belief in the efficacy of preventive vaccines in childhood.

It is the adult vaccines where we do miserably, hepatitis B, the pneumococcal vaccines, influenza vaccines. There is not the same tradition and custom in giving vaccines to adults.

So I think part of the answer to this is going to be to whom will you administer it and for whom will it be recommended, and then to see the record of how you achieve immunization with it.

The CHAIRMAN. Dr. Fauci, what can you tell us about when this vaccine is developed in terms of phase I? Are they going to immunize those without the antibodies or those with the disease?

Dr. FAUCI. Again, that will be a matter of policy based upon advice from a number of sectors. There are pros and cons to each from a scientific standpoint which I can address very briefly for you.

The CHAIRMAN. Sure.

Dr. FAUCI. Excluding phase I or phase II testing, the pro of immunizing an individual who is not yet infected is that, in fact, you may prevent the acquisition of the virus and thereby prevent the development of the disease it causes.

Vaccination of only uninfected individuals does not do anything for those million or more individuals right now in this country who are already infected.

One of the potential positives of immunizing individuals who are already infected is that you may be able to prevent the progression to full-blown disease. One of the potential disadvantages is that you do not know what particular new toxic side effect you might see if you rev up an immune system against an agent with which they are already infected.

So, scientifically, there are pros and cons to each.

The CHAIRMAN. Let me ask you, how many people who are not infected do you think are going to line up for this vaccine?

Dr. KATZ. How many people that are not infected?

The CHAIRMAN. Yes, that are not infected are going to volunteer to take this. I mean, do you think that is realistic in terms of a public behavioral kind of thing? Do you think they are going to want to take it?

Dr. FAUCI. I think that you will see—and this is just an opinion that I get from speaking to individuals and groups. I have no scientifically based way of giving you an accurate number, Mr. Kennedy.

The CHAIRMAN. Yes.

Dr. FAUCI. But I can tell you that I feel that there will be individuals within what we currently call the established risk groups who would come forth to volunteer, even though they are not infected. We are well aware that they are interested in participating in research endeavors and that they see the possible benefit to themselves in that they may obtain some protection through immunization.

Dr. MARTIN. I might add that knowing that a potential vaccine is made by recombinant DNA technology and understanding the difference between immunizing with a recombinant vaccine versus a killed or inactivated virus will change the attitude that prevailed at the time of the initial polio vaccination.

The public has to be educated as to what the risks are. The risks are not getting AIDS from the vaccine. Those risks do not exist with the recombinant-derived subunit vaccine. The risks are the side effects.

The **Chairman**. Just a broader question, Dr. Fauci, and the others. Do you see the danger in our society as this endemic plague begins to manifest itself more dramatically in terms of our society where the scientific community is in danger of being stampeded to cut corners in terms of the FDA process and procedures, individuals who will be flying overseas to take advantage of supposed vaccines that are taking place in other parts of the world.

I was around when we had the Laetrile pressure at that time and it was just a little wood fire compared to the kind of fire-blasting that responsible researchers and thoughtful manufacturers and, I think, knowledgeable people would have with this.

Are you concerned about that situation developing?

Dr. **Fauci**. I do not think, Mr. Kennedy, that that will happen. I think we have passed the early phases of the AIDS epidemic when there was such a panic to go to different countries to get drugs—it was an unfortunate time in the sense that there was a perception that there was something available abroad that an individual could not get here.

I think that things now are moving along extremely rapidly in the area of drug development and testing, as well as in the area of vaccine development. I do not really see that there will be a "cutting of corners", certainly not by the FDA and the Public Health Service, and I do not think by any of the other components of society, such as industry and academia.

Things are moving ahead very rapidly, but also the public is becoming progressively more aware and educated as to the truth about the epidemic and its spread and with regard to treatments that may be available.

The **Chairman**. Let me ask Dr. Martin, what should we be doing at the federal government level to help the private sector to try and deal with some of these questions that will very dramatically and significantly affect whether we are prepared to get this distributed in a commercial way, should we get the kind of progress that all of us are very hopeful about.

What should we be thinking about now? What should we be doing to try and get ahead of the curve so that we are not just reacting somewhere down the road in a way that might not make sense in terms of an orderly, rational response from the private sector and in important, positive impact in terms of the health of the American people?

Dr. **Martin**. Senator, I think from the scientific point of view, the two specific things I mentioned; that is, to support those federal agencies that are starting to develop repositories for virus isolates and patient sera, and, secondly, to promote the serotyping of these isolates, would be two things that would help not just private industry, but every scientist involved in this effort towards vaccine development.

In terms of the marketplace, when Dr. Baltimore and his colleagues were in San Francisco at the IOM hearing, one of the points that I made, as did the representative from another biotechnology company, was that rather than having federal funds put into a program within private industry, a much more effective way and, actually, more American way to deal with that is to provide us with a purchase order for a given number of doses for a FDA-approved vaccine; that is, guarantee us the marketplace and give us liability protection from non-negligent actions.

The **Chairman**. You know, when you mention that, I remember back years ago an item that affected my own State. They had the scare about various sprays that were put on cranberries, and what the military did was they pre-bought their cranberries for Thanksgiving that they would need and they used it all up. It was a sound investment, but it basically saved an industry.

But what we are talking about here is doing this in a logical, thoughtful way on something which we know we are going to face over a long period of time and giving some degree of predictablity to the private sector and some reliability, and an investment where marginal resources now will be enormous in terms of the consumer and in terms of the federal government over the period of the future.

That is the kind of thinking that I would hope we would have. I am not sure that we have got it right now, but it is an important point and I am glad you made it.

We have heard this morning about a world wide health problem of enormous scope and historic significance. It is the first epidemic to threaten both industrialized nations and developing countries.

The global nature of this problem must further impress upon us the need to approach AIDS in a spirit of urgency and cooperation. We must all turn our attention to this problem in govenment, at the workplace, the private sector, the schools, churches, the family and there is no room for stigma and scapegoats.

Let us come together with humanity, dignity and commitment. I am grateful to all of those who appeared this morning and helped us here on this Committee to be able to guide our colleagues in the Senate.

I take a certain sense of pride in my own state of Massachusetts. We have begun funding for some home health care and for support services, which are outpatient treatment, residences for displaced AIDS victims, and a network of help for AIDS persons. This seems to me to be the first state that has taken this as comprehensively as it has.

We are interested in noting the work that has been done in California in a co-related area in terms of Liability. These are all constructive steps to be taken and all of us can profit from knowing about them.

I am grateful to our panels here this morning, and in think that you have gathered from the tenor of the discussion here that we are very supportive of the efforts that are being undertaken in the research area in the private sector, and we are hopeful that you will continue to feel that you can communicate with us in ways that we can be more helpful to you in this area as we address this national and international challenge.

We have a statement from Senator Stevens which we will put in the record.

[The prepared statement of Senator Stevens follows:]

TESTIMONY OF SENATOR TED STEVENS

BEFORE THE

SENATE COMMITTEE ON LABOR AND HUMAN RESOURCES

January 15, 1987

Mr. Chairman,

I want to thank you for giving me the opportunity to present my views on the issue of AIDS, the Acquired Immune Deficiency Syndrome.

As you know, I've introduced a bill, S. 63, to establish a National Commission on AIDS. I believe my bill is essential if we are to effectively mobilize our resources against this deadly disease.

Infections in the highly lethal HTLV-III virus have now reached epidemic proportions. Projections for the next five years of the epidemic -- 179,000 deaths and 270,000 cases have been widely publicized by the Surgeon General, Dr. Everett Koop. Other scientists predict even larger numbers of deaths and cases. By 1991, AIDS will add from between $8 to $16 billion to our annual health care budget. No vaccine is currently available. And fundamental features of the virus and its pathology remain to be discovered. It is estimated that more than 1 in 10 Americans may be infected by this virus in the foreseeable future.

A constantly increasing population of AIDS patients will severely burden our health care system and cripple our armed services. As Chairman of the Defense Appropriations Subcommittee, I worked closely with several prominent scientists involved in AIDS research and sponsored a medical testing and research program sponsored by the Department of Defense.

The Army, as lead agency for the Department of Defense's AIDS research, is coordinating its efforts with other Federal agencies, including the National Institutes of Health. Despite these cooperative efforts, there is a lack of coordinated strategic planning with respect to how we should direct our nation's resources against AIDS -- a fact recently confirmed in a report issued by one of your witnesses today, the National Academy of Sciences.

The time is ripe for us to form a national commission to help us plan and coordinate Federally sponsored AIDS-related programs. The commission that I have proposed would include representatives of all levels of government, the academic community, public and nonprofit private organizations, and the general public. The commission would be charged with comprehensively examining the AIDS issue -- everything from health care to legal issues -- and making recommendations to Congress and the President for legislative and administrative action.

We need to make tough decisions, tempered with a large measure of compassion, in order to fight this disease. A national commission will point us in the right direction.

The **Chairman**. Our Committee stands in recess.
[Whereupon, at 1:08 p.m., the Committee was adjourned.]

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